EXHIBIT D

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE:

) CA No. 01-12257-PBS
PHARMACEUTICAL INDUSTRY AVERAGE
WHOLESALE PRICE LITIGATION
) CA No. 06-11337-PBS
) Pages 1 - 98

DAUBERT HEARING - DAY ONE

BEFORE THE HONORABLE PATTI B. SARIS UNITED STATES DISTRICT JUDGE

United States District Court 1 Courthouse Way, Courtroom 19 Boston, Massachusetts December 10, 2009, 2:10 p.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 7200
Boston, MA 02210
(617)345-6787

	Page 2		Page 4
1	APPEARANCES:	1	PROCEEDINGS
2	CEODCE D HENDEDSON ESO and IAMES I EALICI ESO	2	THE CLERK: In Re: Pharmaceutical Industry Average
3	GEORGE B. HENDERSON, ESQ. and JAMES J. FAUCI, ESQ., Assistant United States Attorneys, Office of the United States	3	Wholesale Price Litigation, Civil Action 01-12257 and 06-11337,
	Attorney, United States District Court, Suite 9200,	4	will now be heard before this Court. Will counsel please
5	1 Courthouse Way, Boston, Massachusetts, 02210. MARK A. LAVINE, ESQ. and ANN ST. PETER-GRIFFITH, ESQ.	5	identify themselves for the record.
	Assistant United States Attorneys, Office of the United States	6	MR. HENDERSON: George Henderson for the United
6 7	Attorney, 99 NE 4th Street, Suite 300, Miami, Florida, 33132.	7	States.
/	RENEE BROOKER, ESQ., United States Department of Justice, P.O. Box 14271, Washington, D.C., 20044.	8	MR. LAVINE: Mark Lavine with the U.S. Attorney's
8		9	office for the Southern District of Florida for the United
9	JAMES J. BREEN, ESQ., The Breen Law Firm, 3562 Old Milton Parkway, Alpharetta, Georgia, 30005.	10	States.
10	5502 Old Wilton Faikway, Alphaletta, Georgia, 50005.	11	MR. BREEN: Jim Breen for the realtor Ven-A-Care of
11	FOR THE DEFENDANTS:	12	the Florida Keys.
11	DAVID S. TORBORG, ESQ., Jones Day,	14	MS. ST. PETER-GRIFFITH: Ann St. Peter-Griffith, United States Attorney's Office, Southern District of Florida,
12	51 Louisiana Avenue, N.W., Washington, D.C., 20081-2113.	15	on behalf of the United States.
13	JAMES R. DALY, ESQ. and JASON G. WINCHESTER, ESQ., Jones Day, 77 West Wacker, Chicago, Illinois, 60601-1692,	16	MR. FAUCI: Jeff Fauci, U.S. Attorney's office in
14	for Abbott Laboratories.	17	Massachusetts.
15		18	MS. BROOKER: Renee Brooker, U.S. Department of
16 17		19	Justice, Civil Division, Commercial Litigation Branch in
18		20	Washington.
19 20		21	THE COURT: That's a mouthful.
21		22	MR. DALY: Good afternoon, your Honor. James R. Daly
22		23	on behalf of Abbott Laboratories.
23 24		24	MR. TORBORG: David Torborg on behalf of Abbott
25		25	Laboratories.
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first. The government should put him on. He should explain 1 the methodology to me. I don't want to start with cross 2 3 because I don't understand it well enough. This is a tutorial

4 to help me understand it, and then you can cross.

5 Do you have any idea how long it will take you to put 6 him on?

7 MR. HENDERSON: Your Honor, I'll turn it over to 8 Mr. Lavine, who will be handling the Daubert hearing.

9 THE COURT: Mr. Lavine.

10 MR. LAVINE: Judge, it may take -- two hours would get us through in fairly detailed fashion his methodology. 11

THE COURT: Good.

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13 MR. DALY: Your Honor, I was thinking that it might benefit the Court if we had some brief opening remarks just to 14 put what it is that we're attacking and not attacking into context, so I had --

16 17 THE COURT: That's terrific, if you want to, although 18 understand that I did plod my way through the briefs, not the 19 gazillion-page expert report, but I did go through the briefs. 20 So I don't want a really long one, maybe just to highlight it, 21 five or ten minutes a side? Does that make some sense?

22 MR. DALY: Certainly, your Honor.

23 THE COURT: Would you want to do that?

24 MR. LAVINE: Sure, Judge. I can get through in just a few minutes to let you know the key points that we --

extrapolated in situations where he had reliable, verifiable 1 2 data rooted in actual paid Medicaid claims.

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3 Third is that although we're not here to evaluate 4 whether Dr. Duggan reached the correct solution, the correct 5

answer, because Daubert we're looking at reliability, not the 6 right or wrong, the test that Dr. Duggan has performed, his

7 large sample size, his examination of the data and the

suitability and the representativeness, the way he made his

9 different adjustments and the different tests for robustness,

10 have demonstrated that he is right on target, thereby

11 demonstrating that he has used a reliable methodology. In

12 general, his tests have shown an exactitude to within just a 13

few percent of the actual number he's provided in his report.

14 Next, everything that Dr. Duggan has done is

transparent. You're able to see everything that he's done in

16 his work papers. And all of his work is replicable, has in

17 fact been replicated by Abbott. And all of his work is

18 testable. Dr. Duggan has done many tests to evaluate the

19 precision of the work that he's done, as compared to Abbott;

20 they have not actually tested it. But it was fully testable.

21 If they had chosen to do so, they could have tested it.

22 And, last, your Honor, Abbott's nonsystematic

cherry-picked counterexamples are just extremely weak evidence

24 for the points that they're trying to put forth here. This is

25 a universe covering millions and millions of claims over eleven

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THE COURT: Well, since it's actually their motion,

2 the question -- well, why don't you go first, and they can go

3 second, of what you're planning on presenting, almost like an opening, and then what you're planning on focusing on, and then 4

5 we can get into the testimony.

MR. LAVINE: Thank you, Judge.

7 There is five key points that we'd like to demonstrate 8

to the Court in connection with this hearing, that, first of

all, using nonrandom samples are a tried and true method that

are routinely admitted into evidence and used in peer-reviewed

11 publications. We see many references to it. Even in the

12 Reference Manual For Scientific Evidence, they directly discuss

13 the use of nonrandom samples. The key question is the same

whether the selection of the sample is random or nonrandom: Is 14

the sample sufficiently representative of the universe to allow 15

16 for a reliable extrapolation? So we'll show that nonrandom

17 samples are routinely used and admitted into evidence.

18 Number two, that the linchpins of Abbott's motion,

19 this idea that Dr. Duggan, and I quote, "did nothing at all" to 20 evaluate the representativeness of the sample, and that he

21 extrapolated using no data whatsoever, is just completely

22 wrong, a hundred percent directly refuted by the plain facts in

23 the case. Dr. Duggan has considered dozens of different

factors to evaluate the suitability of the samples. He's

tested his methodology in many different ways, and he only

years, over fifty different public healthcare programs,

forty-four different NDCs. You can find an example of almost 2

3 anything. To evaluate whether or not the samples were

4 representative, you need to do a systematic review. You need

5 to look at the overall makeup of the sample and the overall

6 makeup of the population, and zeroing in on cherry-picked

7 counterexamples just sheds very little light on that.

THE COURT: Let me ask you this. The thought occurred to me as I was wading through this very dense discussion: Why

10 can't the government, if there's a false claim, just go on

11 penalties? Why am I trying to figure this out?

12 MR. LAVINE: Well, we always try to start --

13 THE COURT: In other words, you get \$5,000 to \$11,000

14 per claim, right? 15

MR. LAVINE: Yes. We have some pretty solid evidence 16 where Abbott -- because Abbott ran their own pharmacies, and we

17 have calculated they submitted enough claims to generate just

18 from their own formula.

19 THE COURT: So you're saying you don't get the -- it's

20 a False Claims Act case, right?

MR. LAVINE: Yes.

22 THE COURT: So for every claim there's a penalty,

23 right, a false claim that they caused to be produced, right?

24 MR. LAVINE: Yes. I completely agree.

25 THE COURT: If I'm understanding it. This is so

	Page 10		Page 12
1	complex that I was sort of wondering why you didn't just rely	1	MR. LAVINE: It depends on the state.
2	on the penalty provision.	2	THE COURT: All right. And you have that for thirty?
3	MR. LAVINE: Well, it just seemed to be a reasonable	3	MR. LAVINE: Approximately.
4	approach to try to calculate the damages.	4	THE COURT: Okay. And then
5	THE COURT: But does it matter?	5	MR. LAVINE: The next level of data is, in the
6	MR. LAVINE: Dr. Duggan was able to	6	ordinary course of the operation of the Medicaid program, each
7	THE COURT: Excuse me. Does it matter? In other	7	individual state reported their drug reimbursement information
8	words, is there a dollar difference?	8	to the Medicare I'm sorry to CMS.
9	MR. LAVINE: Well, sure. Our individual our single	9	THE COURT: Right.
10	damage calculations are approximately \$106.5 million.	10	MR. LAVINE: And we have that data that covers all
11	THE COURT: So what would it be if it was a penalty?	11	fifty states.
12	MR. LAVINE: The penalties associated with the claims	12	THE COURT: And that's what?
13	that tie to that \$106 million in damages would be extremely	13	MR. LAVINE: There's two types of data that do that.
14	high. I haven't actually calculated that because I know it's	14	One is called SMRF, S-M-R-F, or SMRF/MAX.
15	billions of dollars, and we have tried to focus a little bit	15	THE COURT: Like the little blue guys who run around?
16	too in the penalty side on because Abbott had their own	16	MR. LAVINE: Right.
17	pharmacy and submitted claims directly to Medicare and Medicaid	17	THE COURT: All right, so SMRF/MAX and
18	for these drugs, just those claims would be 350	18	MR. LAVINE: And then the third set is called SDUD,
19	THE COURT: The second question I didn't understand	19	S-D-U-D, the State Drug Utilization Data.
20	based on all the papers, and I should have, I'm sure I was	20	THE COURT: And I couldn't figure out what the
21	often reading them at night so there are claims of	21	difference between those two was. It wasn't clearly explained.
22	spoliation. Is any of the data that we're talking about here,	22	MR. LAVINE: Well, the SMRF/MAX data is claim-by-claim
23	when he says he only does ten states instead of the remaining	23	data. You can see a single prescription, the amount billed and
24	states, is that because the data didn't exist, or is it because	24	paid.
25	he just chose to do ten states? If I told him to do every	25	THE COURT: And we have that for all fifty states,
	Page 11		Page 13
1	single state, is the data there?	1	right?
2	MR. LAVINE: We were able to collect directly from the	2	MR. LAVINE: Well, not for every time period, but the
3	states data from approximately thirty states.	3	combination of the three types of data gives us data for all
4	THE COURT: So for thirty states, you could actually	4	fifty states. And if Dr. Duggan didn't have at least one of
5	do this state by state?	5	those three sources, he of course did not calculate any
6	MR. LAVINE: Yes, except the effort involved with	6	damages. He would only calculate damages if
7	mastering the nuances of the data sets of each of these	7	THE COURT: So SDUD is so SMRF is for how many
8	individual states, it's quite extensive.	8	states do you have it?
9	THE COURT: I understand, but we are talking about	9	MR. LAVINE: The SDUD and the SMRF/MAX both cover all
10	billions of dollars, so I'm just trying to understand.	10	fifty states.
11	MR. LAVINE: Sure.	11	THE COURT: And is that all he really needs to
12	THE COURT: So I want to understand what you have and	12	
13	you don't have. You have data. Is that the SDUD data?	13	MR. LAVINE: Well, what he did was to focus on the
14	MR. LAVINE: There's three types of data.	14	claim-by-claim data from the states to do his most detailed
15	THE COURT: Yes.	15	analysis, and then extrapolated using the SMRF/MAX and the SDUD
16	MR. LAVINE: We have the data collected directly from	16	data.
17	the states.	17	THE COURT: All right, that's what he's going to tell
18		18	me about?
	THE COURT: And that's called what?		
19	MR. LAVINE: The state-produced data.	19	MR. LAVINE: Right, right. And that's why we say he
19 20	MR. LAVINE: The state-produced data. THE COURT: That's just called state-produced data.	19 20	had data underlying every penny of the damages because the SDUD
19 20 21	MR. LAVINE: The state-produced data. THE COURT: That's just called state-produced data. MR. LAVINE: Right.	19 20 21	had data underlying every penny of the damages because the SDUD and the SMRF/MAX reflect actual Medicaid claims paid by the
19 20 21 22	MR. LAVINE: The state-produced data. THE COURT: That's just called state-produced data. MR. LAVINE: Right. THE COURT: And you have that for how many states?	19 20 21 22	had data underlying every penny of the damages because the SDUD and the SMRF/MAX reflect actual Medicaid claims paid by the state.
19 20 21 22 23	MR. LAVINE: The state-produced data. THE COURT: That's just called state-produced data. MR. LAVINE: Right. THE COURT: And you have that for how many states? MR. LAVINE: Approximately thirty.	19 20 21 22 23	had data underlying every penny of the damages because the SDUD and the SMRF/MAX reflect actual Medicaid claims paid by the state. THE COURT: So when Abbott and the others complain
19 20 21 22	MR. LAVINE: The state-produced data. THE COURT: That's just called state-produced data. MR. LAVINE: Right. THE COURT: And you have that for how many states?	19 20 21 22 23 24	had data underlying every penny of the damages because the SDUD and the SMRF/MAX reflect actual Medicaid claims paid by the state.

Page 14 Page 16 1 MR. LAVINE: Yes. thirty states of the claim-by-claim? 1 2 THE COURT: You have everything else? 2 MR. DALY: Yes, and they decided not to prove up their 3 MR. LAVINE: There are theories along the line because 3 case on a state-by-state basis. 4 we --4 THE COURT: But you've had access to it, in other 5 THE COURT: No, I understand, but it's the first 5 words, to discredit it, is that right? 6 category of the three, that's what's not there? 6 MR. DALY: Well, in certain circumstances, yes, Judge. 7 MR. LAVINE: Yes, right. 7 THE COURT: All right, so you've both had access to 8 THE COURT: The second two categories exist? 8 the first category, the claim-by-claim, right? 9 MR. LAVINE: Yes, but, again, and there's charts in 9 MR. DALY: Well, except for that it's gone, Judge. 10 the expert report that show --10 Most of the data from the states --11 THE COURT: Yes, but the expert is like this, okay? THE COURT: I thought you said you had it --11 12 MR. LAVINE: Right, I understand. 12 MR. DALY: We've got some. 13 13 THE COURT: Okay, so let's --THE COURT: -- for thirty states. 14 MR. LAVINE: But I want to make sure you understand. 14 MR. DALY: Twenty-five or so. But they have it too. The data, the SDUD and the SMRF/MAX, for example, might not 15 15 We all have that. We all have that. cover a certain state for a certain period, or the SMRF data 16 16 THE COURT: All right, for thirty states, you all have 17 might and the SDUD doesn't. It's the combination of the three 17 it. What's missing are twenty states. 18 databases that was used by Dr. Duggan, where he could use one 18 MR. DALY: Correct. to check on the other, and only did calculations if he had at 19 19 THE COURT: All right, and maybe the District of 20 least one of those sources. 20 Columbia, I don't know. So, all right, and then you all have 21 THE COURT: All right. Well, I'll ask him about that. 21 the data with respect to the aggregate that's at CMS, right? 22 22 Thank you, thank you. MR. DALY: Right. 23 All right, so from Abbott's point of view? 23 THE COURT: And you say that you need to go into the 24 24 MR. DALY: Your Honor, to pick up where you left off, weeds with respect to the thirty states? 25 our problem with the data that we're raising is that the claims 25 MR. DALY: Yes, Judge, and because what Dr. Duggan Page 15 Page 17 does and what the government does is, they take the detailed data, the state-produced data, he only had for ten states. 1 1 That's the data that brings you down to the transaction level 2 analysis of the ten states, and then they extrapolate that to 3 the other thirty-eight. And what they use is the SDUD and the 3 that actually allows you to look at the transaction and 4 determine what the dispensing fee was, how much was paid, how 4 SMRF data. The SDUD and the SMRF data is aggregate. So what 5 much was charged, whether it was a U and C, whether there was a 5 they do is, they say: Okay, here's my ten states, the only 6 MAC, et cetera, et cetera, et cetera. 6 ones I care about, and I'm going to go ahead and look at these 7 7 states. And instead of doing any state-by-state analysis for Our problem that we raise with respect to Dr. Duggan on the one hand and spoliation on the other is that there's the other thirty-eight, I'm going to take my ratio of 9 only ten states of it that they used in the expert analysis. 9 difference for these states, and I'm going to extrapolate it to There may be as many as twenty or twenty-five -- I don't think 10 the SDUD and SMRF data, which is simply aggregate. It tells 11 it's thirty -- states where the data was available. 11 you quarter by quarter by NDC that, you know, Oklahoma spent 12 12 THE COURT: Where the data --\$500,000 on vanco. And so they take this ratio that they MR. DALY: The claims data, the state-produced claims calculated based on the ten states, and they apply it to the 13 13 14 14 other without actually looking at the claim data, without data was available. 15 THE COURT: For thirty states? 15 looking to see whether there are MACs involved, the U and C 16 MR. DALY: I don't think it was quite thirty. It was 16 charges, without looking at the state's formula, because the 17 17 more like twenty or twenty-five. But the point is that SDUD data and the SMRF data don't allow you to do that. And Dr. Duggan didn't use it. He only used ten. And when you move 18 18 perhaps the best proof of that --19 to the extrapolation, the SDUD data and the SMRF data, that's 19 THE COURT: Well, you gave me a very good example, but 20 simply aggregate data, so --20 you gave me one or two. So the question is, have your experts looked at it to show that those are -- looked at another state 21 THE COURT: But you've had access to the state data, 21 22 22 or another five states, since you had it too, to show that -though, right? 23 MR. DALY: We did. In fact, some of the stuff that 23 MR. DALY: We have --24 Dr. Duggan used is stuff that we got pursuant to subpoena. 24 THE COURT: I mean, it is cherry-picked. Now, maybe 25 THE COURT: So you both have similar access to the it's representative or maybe it's not, but it was hard to tell

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Page 18

1 from the brief.

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MR. DALY: We have done a variety of examples that our experts are going to talk to you about.

THE COURT: All right, so that's what I'll be hearing, whether or not those cherry-picked examples, which make your point, are idiosyncratic or whether they're representative.

MR. DALY: Right, and they're not. And some of the examples come from Dr. Duggan's own work, so we'll be using stuff that he discovered that basically show the point of the extensive variation and variability between states. I mean, he calculates ratios of difference for the same NDC, for the same drug, for the same quarter. In one state it might be a 12 13 3 percent difference that he charges as damages to us. In another state it might be 90 percent. 14

15 THE COURT: So can I ask you the other question I started him off with? 16

17 MR. DALY: Sure.

18 THE COURT: If you win, you know, other than in these 19 10 states, isn't it apparent victory because I don't then just

20 apply a penalty per claim?

21 MR. DALY: Well, there's a battle to be waged on that, 22 as you might expect, your Honor.

23 THE COURT: Which is what?

24 MR. DALY: What the cases say is that --

25 THE COURT: I mean, even if I went down to \$5,000, the 1 is probably -- I'm just going to read from two sentences from

Page 20

Page 21

2 his affidavit that he files, and what he says is that "As I

3 explain in my rebuttal report, quote, 'What I've done is not a

4 random sample of the entire universe of fifty states. I chose

5 to focus on the larger states to obtain the maximum amount of

precision. Put simply, it is more important to the total value

7 of the damages to be as accurate as possible for the state of

8 Florida than it is in the state of Vermont."

And so what Dr. Duggan is telling you is that he put more rigor into the 10 states because when he chose his sample, which isn't a random sample -- it isn't any kind of sample at all -- he just wanted to look at the big states, and he didn't

13 care very much about Vermont and New Hampshire and Oklahoma

14 THE COURT: Well, have you done an analysis of Vermont 15

and New Hampshire and Texas?

16 MR. DALY: I don't know that we have the data for 17 that. There's information about Texas, the point being, he

18 himself says, "I don't have the same degree of rigor on those

states because I didn't care about them very much," compared to 19

20 a big state like Florida or a big state like Illinois. And

what we're saying is that if they're going to assess damages --

22 it's their burden to prove damages -- if they're going to

23 assess damages against us, the dollar that Abbott has to pay,

24 if it comes to that, for Vermont is just as valuable as the

dollar for Florida, and it ought to be having the same rigor.

Page 19

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lowest range, it's still doing better than the difference.

MR. DALY: Well, we don't know that because what the

cases say, Judge, in an FCA claim is that the penalties are 4 assessed not on claims, not by claims filed by doctors, but on

5 the defendants' acts. So what the cases have come out, the

6 state cases that we've looked at that your Honor is aware of

7 that have been decided, what the courts have done there is,

8 they don't look at every claim that was submitted by a third

party. They look at the defendants' acts, and the defendants'

acts are, allegedly, the submission of prices to the compendia; 10 11

and that may happen once a quarter, or it might happen once a 12 year. So that's why --

THE COURT: Oh, I see. So that's the debate --

14 MR. DALY: That's why the government is not --

15 THE COURT: -- whether you get a one \$11,000 hit or 16 whether you get it per claim.

MR. DALY: Correct.

THE COURT: And that's why it's worth it to go through 18 19

this exercise because there's at least some legal confusion

20 about what I'd look at.

21 MR. DALY: Yes, your Honor.

22 THE COURT: All right.

23 MR. DALY: There will be a dispute on that, but, yes.

24 THE COURT: Okay.

25 MR. DALY: And our problem with what Dr. Duggan does THE COURT: Take New York and Vermont which are

2 adjacent to each other, I mean, why wouldn't it be reasonable

3 to say, assuming that their regulatory schemes are similar,

4 that you could extrapolate from one to the other?

MR. DALY: Well, interesting question, and we'll get into that, but the OIG and Dr. Duggan himself have seen in the

7 work that he's done that the same states with the exact same

8 exact formula -- let's call it AWP minus 10 -- can have wildly

9 different reimbursements by NDC, by quarter. So you have the

10 same state AWP. One state, he calculates a 30 percent

11 DIFF-FRAC, he calls it, or a ratio of difference; and the state

12 with, you know, two over that has AWP minus 10, they're

13 calculating it at 80 or 90. So the fact that a state has the

14 same formula doesn't mean anything, and there are OIG studies

15 which we'll get into very briefly as well which go into this in

16 great detail.

17 THE COURT: All right, but let me ask you, has your

18 expert done a study that shows that it's completely out of

19 whack comparing the average of these ten, if that's what it is,

20 with, let's say, some of the other states?

21 MR. DALY: Yes, your Honor.

THE COURT: Okay, I shouldn't have said "out of whack."

23 I guess that's a --

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24 MR. DALY: Well, no, I do that all the time.

25 THE COURT: "Out of whack" might have a -- but,

Page 24 Page 22 anyway, so you're going to tell me about that. which we feel has gone beyond the data, and that's our point 1 1 2 MR. DALY: Yes. 2 here. 3 THE COURT: All right. 3

4 MR. DALY: And so just to talk a minute about 4 qualifications? 5 5 MR. DALY: No, your Honor. extrapolation, there's two kinds of extrapolation going on here

when we talk about Medicaid; and even for the 10 states that 6 6

7 Dr. Duggan has, he does not have data for all the years, even 7

8 for those states. And so you'll see we'll have charts --

9 THE COURT: Yes, but that's less hard for me. I mean, 10 you know, this question of if you've got ten quarters, can you extrapolate to the next fifteen, that's less hard than across 11

12 13 MR. DALY: Well, okay, and I think that there are gradations of reliability here. But in that, if you take 14 15 Michigan, for example, which is one of the 10 states that he uses, he only has five quarters, and those are 2001 and the 16 17 last quarter of the year 2000. And he extrapolates those five 18 quarters ten years back all the way to 1991, and so you've got 19 basically nine years of the damage period being extrapolated

20 from the very most recent five quarters. And what you end up with -- so there's an example --21 22 THE COURT: You know, actually, I really don't want to

take up too much more time. I read your briefs. I mean, so the four kinds of extrapolation, are we talking about, is

extrapolation across states?

THE COURT: And you're not challenging his

THE COURT: Okay, good. Let's hear from him.

MR. DALY: Thank you.

8 MR. LAVINE: Your Honor, may I take one minute to

9 respond?

10 THE COURT: No. Let's just do it. All right, I'm

11 sure he's a busy man, right? He's taking care of the whole

12 Healthcare Bill, so let's get him out of here, all right,

13 because I'm hoping here, it's 2:35, you're going to take two

14 hours, is that it?

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MR. LAVINE: Probably.

16 THE COURT: So if you can do an hour and a half, and 17 we're going to need to do a break for the Court Reporter, so we

just need to move through this. 18

19 MARK G. DUGGAN

20 having been first duly sworn, was examined and testified as

21 follows:

22 THE CLERK: Would you please state your name and spell

23

24 THE WITNESS: Dr. Mark Gregory Duggan. It's spelled

25 M-a-r-k G-r-e-g-o-r-y D-u-g-g-a-n.

Page 23

DIRECT EXAMINATION BY MR. LAVINE:

2 Q. Dr. Duggan, just briefly, can you give the Court the

3 benefit of your --

4 THE COURT: I've seen the CV. Let's just get to the

5 merits. He's qualified.

6 MR. LAVINE: All right, thank you.

7 Q. Dr. Duggan, what is your understanding of why we are here

8 today?

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9 A. It is a Daubert hearing, and that there are certain

components of my analysis that Abbott and Abbott counsel are

11 challenging, and I'm here to discuss the reliability, the

12 validity of the methodology that I deploy in my analyses.

13 THE COURT: Let me ask you this: Have you ever

14 testified before?

15 THE WITNESS: I have not.

16 THE COURT: All right, so sit back, relax. All right,

so the key is -- do you teach undergraduates at Maryland?

18 THE WITNESS: I do.

19 THE COURT: All right, I'm an undergraduate for this 20 purpose, so when you're starting to talk statistical concepts,

21 I had one undergraduate course in statistics, so if you can

break it down and talk to me more than you do the lawyers. 22

23 THE WITNESS: Okay, and look at you.

24 THE COURT: Yes, you're teaching me what happened 25 here, all right?

1 MR. DALY: Yes.

2 THE COURT: Extrapolation within states, right?

3 MR. DALY: Yes.

4 THE COURT: There's extrapolation across carriers, and

5 there's extrapolation within carriers, right?

6 MR. DALY: Exactly.

7 THE COURT: All right, so those are the four things 8 that you're challenging?

9 MR. DALY: Yes, your Honor.

10 THE COURT: Is there anything else you're challenging?

11 MR. DALY: No, your Honor, and I did want to point out

12 that when you get into Dr. Duggan's numbers -- so we're not challenging a lot here. The states where he has the data 13

before he does the in-state extrapolation, we're not 14

challenging that. There's no Daubert challenge. We have a lot 15

16 to say about that on the merits at trial, but for Daubert,

we're fine with that. We challenge the in-state and then the 17

18 across-state.

19 The same thing on the carriers. Where he has the four 20 or five carriers where he has the arrays, even when he doesn't

21 have arrays for every J-Code that he's calculated, we're not

22 challenging those. And in each case it ends up being about 23 50 percent of the damages for Medicare and 50 percent of the

damages for Medicaid. And I wanted to make that point because

we're not challenging everything. We're only challenging that

Page 26

1 THE WITNESS: Okay.

- 2 Q. What is your understanding of the key critiques leveled by
- 3 Abbott at your study, at your analysis?
- 4 A. I think that they were just described, outlined by counsel
- 5 to some extent, the notion being that -- I think the criticism
- being that the extrapolation methodology that I utilize in my 6
- 7 analyses is unreliable and not valid; it's at a high level.
- 8 Q. And in particular, what is your understanding with respect
- 9 to the data?
- A. Well, my reading of the various documents that they've 10
- submitted and their experts have submitted indicates that they 11
- have a sense that I'm extrapolating to periods or products or 12
- 13 states and what have you for which I have no data. And in this
- report, your Honor, you may have seen that I deploy quite a lot 14
- 15 of data, and I think that is flat out wrong.
- 16 Q. And then in connection with the representativeness of the
- 17 sample, what is your understanding of the particular point
- 18 they've leveled there?
- 19 A. Well, once again, my reading, sort of aggregating up all
- of the documents and so forth, is that Abbott and Abbott
- counsel are claiming that I've done really nothing to gauge the 21
- appropriateness of taking results for this very large sample of
- claims to estimate what the corresponding "difference," as I
- call it in the report, and I can define that later, would be in
- this group of claims that are outside of the sample.
- Page 27
- Q. So do you agree or disagree that you did nothing and
- 2 extrapolated with no data?
- 3 A. I disagree.
- 4 Q. And can you characterize the thoroughness of the work that
- 5 you performed.
- 6 THE COURT: No. Let's just explain it. What did you
- 7 do?

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- 8 Q. Well, what were you asked to do?
- 9 A. In my judgment, having done years and years of work on
- Medicaid/Medicare and similar sorts of government programs,
- 11 healthcare issues, I did an enormous amount to assess the
- 12 validity of this methodology, and I can -- I don't know when we
- 13 want to sort of drill down.
- 14 THE COURT: Now.
- 15 THE WITNESS: Okay.
- 16 THE COURT: So start really with baby steps. What
- 17 data? What did you do? What was the methodology?
- 18 THE WITNESS: Okay, great. So two programs at issue
- 19 that I'm analyzing really in this report, the Medicaid program
- 20 and the Medicare program. For Medicaid, I utilized three
- 21 different sets of data, as counsel explained earlier: the
- state-produced claims data for states like Florida, California, 22
- New York and so forth; the CMS claims data for the remaining 23
- 38 states; and the CMS S-D-U-D data, SDUD data. And just to
- give you a sense of the sort of level of information that's

- contained in these different files, so the state-produced
- 2 claims data and the CMS-produced claims data are very similar.
- 3 There are some discrepancies, there are minor discrepancies,
- 4 but basically there's a claim per -- for the typical
- 5 prescription that gets dispensed at a pharmacy, a claim is
- 6 going to appear in both of those data sets, if I have the data 7
 - for them.

8 The S-D-U-D data, the State Drug Utilization Data, is

- 9 aggregate data by state, by NDC, by quarter. And so in
- 10 thinking about what sort of level of information is here --
- 11 (Discussion off the record.)
- 12 THE WITNESS: So 50 states, 44 products, 44 quarters,
- 13 okay. So that's basically, in terms of how many observations
- 14 are in this data, it's essentially 50 times 44, times 44, which
- 15 is approximately 100,000.
- 16 Now, some of those cells will be empty. Maybe Alaska
- 17 won't have any utilization for a particular product in a
- 18 certain quarter, but that's to give you a sense of sort of
- 19 order of magnitude. So while the term "aggregate data," it is
- aggregate data, it's still at a very fine level. Because it's 20
- 21 100,000 different cells on three million claims, it's --
- 22 THE COURT: A hundred thousand different --
 - THE WITNESS: Cells. When I say cells, I mean like
- 24 state NDC quarter combinations. And some of those cells, those
- 25 combinations will be empty, there won't be any claims. But for

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Page 28

- 1 many, tens of thousands of them, there are.
- 2 THE COURT: And is there a difference between the
- 3 state-produced data and the CMS claims data which you say you
- 4 have for 38 states?
- 5 THE WITNESS: There are some differences between the
- 6 two.

23

- 7 THE COURT: Like what?
- THE WITNESS: So, for example, the units variable that 8
- 9 is -- so one of the things, if one's looking, sort of looking
- 10 at a claim and trying to replicate, how did this methodology
- 11 arrive at \$60 paid, and so the state-produced data does have
- typically a units field, which can be multiplied by the AWP and 12
- 13 then times .9 or .95, depending on the state. So there's a bit
- 14 more detail in there, a units variable that's included in
- 15 across the years, things like, typically the dispensing fee is
- 16 broken out and so forth, so there's a bit more detail in it.
- 17 But, also, many of the things that are in the claims
- 18 data are also in the CMS data. So, for example, the paid
- 19 amount is in both sets of data. The usual and customary, the
- 20 sort of charged amount, that's in both sets of data. The
- product is in both sets of data, the state, the quarter. There
- 22 are many things that are common, but there are a few minor
- 23 differences.
- 24 THE COURT: Is the MAC in both, whether there's a MAC
- 25 used, a maximum allowable cost?

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Page 30

THE WITNESS: No, but to some extent, the MAC would be embedded in the paid amount, but there isn't necessarily a MAC indicator in the SMRF/MAX.

4 THE COURT: Because that's all that -- that's what you 5 pay? That's why it's in the embedded amount?

6 THE WITNESS: That's exactly right, so if there's a 7 MAC of 30 in effect --

8 THE COURT: Could you tell that? In other words, so 9 if you don't have the state -- the state data will give you whether there's a MAC, right? 10 11

THE WITNESS: Typically, yes.

12 THE COURT: So if you're looking at the federal data, 13 the CMS data, and you don't know whether there's a MAC or not, can you look back to the regulatory scheme to find out whether 14 in fact they're following a MAC. Would you be able to go --15 16 for example, Massachusetts in a given year might say, "This is 17 our MAC"?

18 THE WITNESS: Right, so it is possible to back out 19 this kind of information in certain instances, and to the 2.0 extent that these -- so it's possible, and certainly a look at the adjudication methodologies used by the states can shed some 21

light on this. But, also, to the extent that a state pays a

MAC, let's say, that would be less than what would end up from

AWP, for example, that will be reflected in the paid amount,

and so that is sort of -- I don't know where -- there's so many

of the kind of thing that I did to assess the comparability of 1

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2 the two states. It turns out that more often than not -- and

3 this is true even when I pull Ohio from the analysis, which we

4 can talk about -- the average amount paid in the 10 is -- I

5 have to go back to my footnote --

MR. LAVINE: Your Honor, I have copies of the report.

THE WITNESS: I'm looking at Footnote 45.

8 THE COURT: I am sure I didn't read the footnote.

9 THE WITNESS: Yeah, right, so it's the average

10 reimbursement -- I just don't want to flip it.

11 THE COURT: Well, Which footnote are we talking about?

12 THE WITNESS: It's Footnote 45 on Page 78.

MR. LAVINE: Your Honor, No. 1 would be the beginning 13 14 of the exhibits to the initial report, Tab No. 1.

THE COURT: Yes, well, I've got 45.

16 THE WITNESS: Yes, it's in Tab B, I think?

17 THE COURT: Yes, I've got it.

18 THE WITNESS: So it's around Page 78. And so you see

19 there in that footnote I'm describing how basically I'm

20 looking, on a per-claim basis, how does reimbursement, looking

for each of the 44 products, differ for those 10, the Floridas 21

22 and so forth, versus the remaining 38, the Vermonts? And if

23 anything, it appears from this comparison that average

24 reimbursement per claim, it's more often than not it is higher

25 in the remaining 38.

Page 31

elements, so I'll just sort of go into this because I think

2 this is useful.

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3 One of the things that I did to assess the 4 comparability of those 10 states for which I used 5 state-produced data to the 38 is, I look: For the 44 products 6 that are at issue in this case, are the average amounts paid per claim comparable between the two groups on average? So is it the case that --

9 THE COURT: Between what two groups? 10 THE WITNESS: The 10 and the 38. And here if you -- I 11 don't know if you have the report in front of you. 12 THE COURT: I don't have it right in front of me.

13 THE WITNESS: Yes, no, that's okay. If not, I can 14 just explain. So there's a period of time when I have the CMS claims data for all of the states, for all of the essentially 15

16 48, 49 states that are being analyzed; and I can see, is it the

17 case that systematically there's a systematic pattern? Is

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there a difference in the sense that the 10 states tend to 18 reimburse more per claim than the 38? 20 So it would be -- suppose it were true that I found 21 that on average, the 10 states paid \$50 per claim for one of the vanco NDCs, but the remaining 38 states were paying \$10 per claim. That would potentially be driven by, those 38 states 23 for whatever reason have much more aggressive MAC programs in effect across the board, right? So this is exactly an example

So if I thought, well, you know, those 38, it's just

2 going to be true that they have much more aggressive MAC

3 programs in effect, I would have expected the opposite in a big 4 way. But, you know, it's basically half the time: 24 more

5 often than not, 24 out of 44 cases, and 23 out of 44 when we

6 drop Ohio; the average amount paid is higher in the 38 than in

7 the 10, suggesting it's not true. And you can -- I'm sure

8 there are examples, so --

9 THE COURT: But on the other part, is the drop 10 dramatic? In other words, you seem to think it all works out 11 in the wash.

THE WITNESS: Washes out.

13 THE COURT: Some term like that. But if one's only 14 slightly higher -- if the majority is more likely the slightly 15 higher and then the remaining are dramatically lower, what do I do with that? 16

THE WITNESS: I don't have those numbers right here in front of me, but what I can tell you is that those products, those 24 out of 44, account for 75 percent of the spending. So

20 the ones where the 38 appear to be -- you know, I don't want to

21 make a huge amount -- it's just they're on average quite

22 comparable. If anything, it looks like, for more products and

23 for more Medicaid spending, the average amount paid per claim

24 is higher in the remaining 38. And I hope that I'll get a

25 chance today to talk about some analyses that I've done in

recent months going out of samples. So let's go to some of 1 1

Page 34

2 those 38 and see how they're --3 THE COURT: So but the big difference between the

- state and CMS data is, you don't get the MACs spelled out and
- you don't get the differences in dispensing fees fleshed out. 5
- Is there anything else that's materially different between the
- two data seats for our purposes?
- 8 THE WITNESS: No. Those are the key ones.
- THE COURT: Those are the two key ones? And so if you 9
- have just the CMS claims data and you don't have the state 10
- data, that would be the question mark. If you have the state 11
- 12 data, you could go back and double-check and find out?
- 13 THE WITNESS: That's true, yes.
- 14 THE COURT: So since we have the state data in 30, if
- 15 we had to, and I know it wouldn't be a joyful task, but if we
- had to, you could at least analyze 20 more states along the 16
- 17 same lines that you've done for the ten?
- 18 THE WITNESS: And fortunately, I don't know that 20

MR. LAVINE: Thank you, although I can tell that he

MR. DALY: Your Honor, I'd like to interpose an

objection. The situation is this: Dr. Duggan has -- well, we

just got some new analysis that he did last Monday after

Thanksgiving. He's already filed four expert reports. He

filed an original, he filed a supplement, he filed a rebuttal.

He filed an affidavit in support of summary judgment. This

hearing has been set for a couple months, and, you know, a week

before we're coming in here, we get some new apparently very

extensive examination that we've had some opportunity to look

at, but by no means the opportunity to dig in and find out what

need a little extra time to have your expert look at it and

A. So basically I sort of -- the initial report, and there

Q. Sorry, go ahead, describe the analysis with respect to the

was a subsequent revision to it, just that revised the numbers

respond to it, of course I will allow that.

9 and the outcome of that.

MR. DALY: Thank you, Judge.

THE COURT: Well, that objection is overruled. If you

- 19 more is -- I think we're in the 20s as opposed to at 30, but
- 20 fortunately, for the 9 states within the 38 for which we had
- the most data, I've since done some analysis. 21
- 22 THE COURT: I see, so beyond the initial 10?
- 23 THE WITNESS: That's right.

witness. All right, go ahead.

wants to continue with that exact point.

Q. Describe a little more about the 9 that you were

24 THE COURT: I see.

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discussing.

it is that he did.

25 THE WITNESS: And so we can assess that.

- a little bit, sort of I really tried in that initial report to
- 2 make it very clear where the big number, the 65 or, you know,
- 3 whatever the large number was, where they were coming from by

Page 36

Page 37

- 4 giving state-by-state summaries and in some cases multiple
- 5 summaries for each state. And so it is straightforward to look
- 6 at the initial report and the subsequent revision, the table, a
- 7 couple of the tables, to see, what did my extrapolation
- methodology predict for the state of, for example,
- 9 Pennsylvania? What did it predict for the state of Virginia or
- 10 Texas and so forth? Because these are states for which I had
- state-produced claims data but did not -- they weren't included 11
- 12 in the original 10. They were not in the original 10, but
- 13 these new 9, how does the extrapolation methodology fare?
- 14 So, for example, in the state of Pennsylvania, my
- 15 extrapolation methodology said 1.2 million, just rounding to
- 16 the nearest --

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- 17 THE COURT: The difference?
 - THE WITNESS: Yes, the federal difference. My
- extrapolation methodology said 1.2 million. And here I'm going 19
- 20 to round just to the nearest 100,000 so --
- 21 THE COURT: Sure.
- 22 THE WITNESS: And the amount doing a claim-by-claim
- 23 analysis -- that's apples to apples with the ones that I did
- 24 for the other 10 states -- 1.1. So it was a little higher for
- 25 that one of the 38.

Page 35

- THE COURT: All right. I've stopped hijacking your 1 For Virginia, 0.9 and 0.9.
 - 2 For Texas -- and Texas actually is interesting because
 - that was one of the states that Abbott counsel criticized me a 3
 - 4 lot for not including them in the original sample -- my
 - 5 methodology yielded 0.9 million, and the claim-by-claim
 - 6 analysis yielded 0.9 million, in fact slightly higher with the
 - 7 claim-by-claim analysis.
 - 8 MR. LAVINE: I'm sorry, Judge, I should have pointed
 - 9 out these numbers are in the last page of Tab E.
 - 10 THE WITNESS: They're in Tab E.
 - 11 THE COURT: All right, give it --
 - 12 MR. DALY: Thank you.
 - 13 THE COURT: This is very useful, but you don't have
 - it, right? 14
 - 15 MR. DALY: Right.
 - 16 THE COURT: Is this what he got last Monday?
 - 17 MR. LAVINE: Yes. The only materials contained in
 - 18 here are copies of the materials already produced.
 - 19 THE COURT: Do you have an extra one for my law clerk,
 - 20 since you seem to have volumes back there?
 - 21 MR. LAVINE: Sure.
 - THE WITNESS: So should I resume? 22
 - 23 THE COURT: Yes.
 - 24 THE WITNESS: So here you can see a detailed, the side
 - by side of each of the 9 states. And aggregating across the

10 (Pages 34 to 37)

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Page 38

9 states, my methodology predicted a federal difference of 1 6.4 million, and the claim-by-claim analysis yielded a 3 difference of 6.0 million, off by 6 percent, approximately 4 6 percent.

I will concede that it was a little higher, that my methodology was a little higher than, like, then the amount that is sort of apples to apples with the amounts from those original 10 states, and so I was curious about that, why is

9 that true? So I drilled down a little bit on those

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9 states, and what I found was that in these 9 states, a little 10

more often -- so if you look between the 38 states and the 11

12 10 states, the frequency with which the two groups pay usual

13 and customary is almost identical. It's like 24 percent for

14 the first 10, 25 percent or 24 point something percent for the 15 other 38.

16 Why does the usual and customary share matter? Well, 17 the differences tend to be lower on claims where usual and 18 customary is paid, and I think it's best for me to give an 19 example. Suppose a formula suggests 60, but a provider charges

40, and my methodology says 15, okay, that if you use the Abbott prices and you plug them into the Medicaid methodology, 21

you get 15, if the usual and customary were higher, then the

23 difference would be 60 minus 15, 45. But if the usual and

24 customary is getting paid, the difference is going to be

smaller, 25, a little bit smaller.

in any case, it's very much --

Page 40

a million. So taken together, it is I think about 1.3 million. 1 2 It's 0.4 and 0.9 would be the adjustment. So if one were to

3 apply the 6 percent across the board to the remaining 29

4 states, it would lower it by about -- the overall difference

5 from -- and let me just see if I have the --

THE COURT: Well, would that be a reliable methodology, to take the 6 percent and apply it across the other states?

9 THE WITNESS: Part of the reason that I drilled down 10 in the way that I did was to see, are these 9 -- it looks like these 9, you know, paid the usual and customary a bit more 11 12 often than the remaining 29, who actually pay usual and 13 customary less often than the remaining 10. So I still think a 14 more accurate estimate of the total difference for those

15 remaining 38 would be the other number, but it's not -- it 16 wouldn't be -- it would be --

17 THE COURT: Well, would there be a way of going into 18 these other states and seeing whether their usual and customary 19 reflects these additional 9?

THE WITNESS: Right, so I think I've actually done --

21 THE COURT: You've done that.

22 THE WITNESS: Yes. So the usual and customary for

23 these 9, the statistic that I recall right here is about

24 27 percent of the time they're paying usual and customary,

versus about 24 percent for the first 10, versus less than

Page 39

And so it turns out that these 9 states pay usual and customary somewhat more than the remaining 29. So part of the reason that I'm off here at all -- I mean, I don't expect it to be exact to the dollar, but part of the reason that I'm off a little appears to be this, this difference between those 9 and the overall 38. But I guess it's useful to know that those remaining 29 look more like the original 10 than these 9, but

THE COURT: How do you know that? THE WITNESS: In terms of this dimension of this usual and customary.

THE WITNESS: How do you know the remaining -- in other words, why wouldn't it make sense just to shift down your extrapolation 6 percent in all the other --

THE WITNESS: Six percent across the board. So I guess there would be a couple ways one could do this. One could say, I'm going to shift down the extrapolation by 6 percent, or, alternatively, that instead of using 10, I'm going to use 19 in predicting. So that would end up shifting down the remaining by about 3 percent, if you do sort of a back-of-the-envelope calculation.

But suppose even you did the 6 percent, you adjusted down the remaining dollars by 6 percent. So here we're talking about I'm off by about \$400,000. If you revised down the remaining amounts by 6 percent, the effect of that is less than

Page 41

1 24 percent for the remaining 29. But you can see, they're 2 very -- I guess the takeaway for me from this -- and I'll 3 concede that I would have preferred 6.4 and 6.4 in terms of the 4 method, like -- "prefer" isn't the right -- but I would --

THE COURT: You would have taken greater academic satisfaction.

THE WITNESS: Right, in being exactly on the money, but being within 6 percent, you know, this is a pretty complicated set of data and so forth, it makes -- you know, to me, it really corroborates the methodology that I've deployed.

11 THE COURT: So what about differences in dispensing 12 fees, which was another big point? There were some huge 13 differences.

14 THE WITNESS: In the dispensing fees.

15 THE COURT: That Abbott sort of highlighted.

16 THE WITNESS: Right, so I can -- I can -- it turns out 17 that these sort of enhanced dispensing fees for the 9, so if we

18 look among the 19 states now, the first 10 in these 9, several

19 of them have these sort of enhanced dispensing fees; and the

20 frequency with which those dispensing fees are paid is actually

21 not all that high. So in terms of, does it make a material

22 difference to the analysis, there are going to be instances

23 where it will matter on a claim-by-claim basis; but in a

24 material difference, it's not a big driver of the total

25 difference. So, you know, it is true that -- and that's

something certainly that I looked at, these dispensing and so 1

- 2 forth, that they do vary to some extent across the states, but
- 3 in a systematic common way, not so much, that is reflected in
- the data.
- 5 THE COURT: Do you want to pick it up?
- 6 MR. LAVINE: Yes, Judge.
- Q. Two quick follow-up points on the data. The SMRF/MAX
- 8 data, is that claim by claim that shows an individual
- 9 prescription in each line?
- A. Yes. Yes, it does, and it's -- yes. 10
- Q. So what is the difference between that and the SDUD data? 11
- 12 A. The SDUD data, the SMRF/MAX data is very similar to the
- 13 state-produced claims data. It differs a bit, as we discussed.
- 14 The SDUD data represents the aggregate number of prescriptions
- and total amount paid per state in a state NDC quarter 15
- 16 combination. And it's helpful, I think -- I don't know, your
- 17 Honor, if you have the report in front of you, but Tables 26-A
- and 26-B give a sense of --18
- 19 THE COURT: And this is in what, Tab --
- THE WITNESS: Under "Reports," this would be in Tab 1. 20
- 21 THE COURT: SDUD.
- 22 THE WITNESS: So here are the 38 states listed in
- 23 descending order of spending for the complaint products, and
- 24 you can see in Table 26-A that the amount of SMRF/MAX data used
- for these 38 states is about 34.5 million, and you can see here
 - Page 43
 - that basically all of the states have data from '99 through
- 2001, with the exception of Tennessee, which was different in
- other ways. But there are some -- and then there are many
- states that go far back. For example, you know, the state of
- 5 Pennsylvania goes all the way back to 1992 with the SMRF/MAX
- 6 But not all of the states have SMRF/MAX data in every year, so
- on Table 26-B I list the SDUD spending and utilization for the
- remaining state years. And the latest this data is used is
- 9 1998 because I have SMRF/MAX always for '99 to '01. But it
- gives you a sense. We're talking about 13.9 million for the
- 11 SDUD data and 34.5 million for the SMRF/MAX for these other
- 12 states.

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- 13 THE COURT: Well, so how do you extrapolate backwards?
- 14 How do we know that, without even the SMRF/MAX data, that
- 15 that's reasonable?
- 16 THE WITNESS: Okay, so what I do in the analysis is,
- 17 for each NDC quarter combination -- and there are about 2,000
- NDC quarter combinations because there's 44 products and 18
- 19 there's 44 quarters -- I essentially take the average of the
- 20 10 states for which I have data and use that in these remaining
- 21 38 states.
- 22 So just as an example, just to give a sense, suppose
- that 5 of those states have an average ratio of difference to 23
- spending of 70 percent in a particular NDC quarter combination --
- so this is really, like, this level of detail. It's not like

- I'm taking a state aggregate and just applying it to another 1
- 2 state aggregate. I'm drilling down to 2,000 separate distinct
- 3 NDC quarter combinations, taking account of the fact that these
- 4 spreads grew over time, taking account of the fact that these
- 5 spreads vary a lot across products, and respecting that
- variation when I try to predict/estimate what the difference is 6
- 7 in another state. And so I take the average of those 10
- 8 states.

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- 9 Now, admittedly, in certain periods, I don't have data
- 10 for all 10 states, so there may be certain and many NDC quarter
- 11 combinations where I only have 9 states or 8 states. But
- 12 underlying that in each of these NDC quarter combinations are
- 13 typically thousands of claims for these states. Then I'm using
- 14 that to predict over -- estimate for this other group. So
- 15 literally for every state analysis, for all -- I do 38 separate
- 16 state analyses where I say, how much vanco 653301 does this
- 17 state have in the fourth quarter of '97, and then I compare
- 18 apples to apples with the other 10 states, try to use that to
- 19 estimate that difference ratio.
 - THE COURT: Would you take an average?
- 21 THE WITNESS: Take an average, I take an average.
- 22 THE COURT: And then have you spot-checked yourself
- 23 the way you did with the other set of data?
- 24 THE WITNESS: No. So that's for the other 38. So
- 25 there's no need for a extrapolation back with the other 38 in

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- 1 the sense that I'm using this average of the 10 states to
- 2 predict for these 38.
- 3 Now, for the 10 states for which I use state-produced 4
- claims data -- now, there are some states where I go back 5 practically to the beginning. I think it's Illinois I have all
- 6 the way back to '91, quarter two. But there are others where
- 7 the data turns on later in the period, and so in that instance,
- 8 what I do -- suppose that we're in a state where the first
- 9 quarter data is 1996 quarter one, okay? And then for that
- 10 state we have excellent data, the population of claims for that
- 11 state in that, say, quarter. And then I calculate the
- 12 difference-to-spending ratio there. Say it's 70 percent, okay?
- 13 Now, what I could have done was just apply that
- 14 backwards, but that wouldn't account for the fact -- and this
- 15 is especially important going backwards -- that spreads are
- 16 growing over time. So if I extrapolated back that
- 17 70 percent, that would overstate the difference on average, in
- 18 my judgment, because it would not account for the fact that,
- 19 you know, the spread in '92 was a lot lower than it was in '98.
- 20 And you can come up with exceptions, but in general it's sort
- 21 of going back. And so I adjust down. So, for example, suppose
- 22 the spread was, you know, in that 70 percent example, suppose
- the spread was only half as high in an earlier period, then I 24 would move that 70 to 35. Now, what's --
- 25 Q. Is that phenomenon -- I'm sorry -- reflected in the

Page 46 Page 48 Figure 1 to your initial exhibit? 1 THE COURT: For all the other? 1 2 THE WITNESS: Other 38. A. That's exactly right, so I think it's helpful to go to 3 Figure 1. What I'm essentially trying to -- it may even be --THE COURT: Excuse me. So the 2 million are for the 10 states, and the other 38 are the 890,000? it may be more useful to go to Figure 2. This would also be in 4 5 5 THE WITNESS: Yes, that's right. And I'm just looking Tab 1. Do you have the figure in front of you? 6 THE COURT: Yes, I do, yes. 6 at the most recent one, so Table 35 behind Tab 2 -- Table 25, I A. Okay, so you can see that the published prices are going 7 mean, behind Tab 2 gives you a sense of this. 8 8 up, while you can also see that the average transaction prices THE COURT: Wait a minute. I just want to make sure 9 9 are falling. So what this extrapolation back in time does is, I've got that right. Table 35. 10 THE WITNESS: No, I'm sorry, Table 25 behind Tab 2. 10 it accounts for that. And, moreover, if for whatever reason when extrapolating back the spread were bigger, I don't account It's the first page behind Tab 2. 11 11 12 for that. So I basically say, I'll only adjust it down going 12 THE COURT: All right, I was in the wrong location. 13 back. So if for whatever reason the spread a year earlier was 13 Okay. 14 a bit higher, I basically take the minimum of whatever -- so THE WITNESS: So if you look at that first row there, 14 15 the total for the first set of states, 2.1 million claims. 15 I'm basically, this is accounting for this method. 16 16 Now, how do I probe the validity of this? And I describe It's a bit lower because some of them are SMRF/MAX, some are 17 this in my rebuttal report. I essentially pretend for each 17 SDUD, but if you aggregate it up, it's in the neighborhood of 18 state that my data started a quarter later than it actually 18 1.8 million. 19 19 did. And what I find when I do that is that the difference THE COURT: No, I'm not seeing. Where are you 20 using the extrapolation is lower aggregated across the states 20 pointing to? 21 THE WITNESS: So the third-to-last row, total for 21 than it is when I use the state claims-by-claims data, 22 consistent with the notion that it's -- essentially it's in a first 11 states, if you look at the number -sense conservative. It can only adjust down that difference 23 MR. DALY: Third to last up and down, Judge. 24 going back in time. I don't ever adjust it up, and consistent THE WITNESS: Third to last from the bottom. 25 THE COURT: Oh, from the bottom. I'm sorry. with that, the pattern is that it is, if anything, having more Page 47 Page 49 1 state-produced data would lead to a higher difference. THE WITNESS: Yes, that's okay. And so you see the 1 THE COURT: When do MACs kick in in most states? Are column that says "Number of Claims," you see 2.1 million for 2 2 3 3 the first 11 states. So here I would want to subtract out MACs even a factor in trying to understand this early on? 4 THE WITNESS: They become a bit more of an issue later 4 Indiana, which is about 200,000. And, you know, when thinking 5 in the period, and they're certainly an issue in Ohio, but Ohio 5 about this, so that brings us down to around 1.9, but, in any 6 wasn't in the ultimate analysis. But during this time period 6 case, you can see that the number of claims in this initial for this set of products -- and, once again, there are examples 10 states is about twice as high as the number in the remaining and there are cases, but systematically this is not, for these 38. And so I'm leveraging an incredible amount of data to form 9 products, it's not -- I don't have the number off the top of my 9 an estimate of this ratio of difference to spending. head, but what I can say is that to the extent that MACs are 10 Q. How does that compare to the size of a more common sample 11 being paid, that will be reflected in a lower difference. And 11 that you might deal with or have seen? 12 12 so that, you know, my analysis -- ultimately, you know, I have A. Well, I think that there are many cases where a much this analysis that drills down the states-produced claims data, 13 smaller sample is used to try to learn something about an 13 economywide or marketwide phenomena. So, you know, if you 14 uses the results from that. Really, and at some level I'm 14 15 using data for almost 2 million claims to form these 2,000 NDC 15 think of Gallup polls that are trying to predict what fraction 16 quarter averages, and then for every one of the 38 states, you 16 of people are going to vote for President, those are often in 17 know, basically lining up their utilization for those 2,000 NDC 17 the neighborhood of 1,000 to 2,000. But closer to this kind of quarter averages and predicting and estimating what the 18 thing, suppose one -- there's a recent study by -- Gruber and 18 19 difference will be. So I'm leveraging an incredible amount of 19 Rodriguez set out to answer the question, how much uncompensated 20 data in this sample, which has, you know, almost 2 million 20 care do physicians provide in the U.S.? And they used a sample 21 claims to estimate difference in a sample with less than a of about 4,000 physicians in their analysis to learn something 22 about how much uncompensated care nationally is provided by million claims going across the states.

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the other states had how many?

THE WITNESS: 890,000.

THE COURT: How much -- your sample had 2 million, and

several hundred thousand physicians. So the ratio, they're

leveraging -- for every one physician in their sample, there
 are, I think, 150 or so physicians outside of their sample, and

Page 50 Page 52

- there are big differences between their sample and the 1
- population of physicians. So, in any case -- and this is a
- 3 study that was published in the Journal of Health Economics,
- which is the leading journal in the field of health economics,
- 5 and it's a very highly regarded study.
- 6 THE COURT: I think we should keep going till about
- 7 3:30 and take a break.
- 8 MR. LAVINE: Sure.
- 9 THE COURT: Unfortunately for you all, I've been on
- trial since 9:00, so I think I'll take a break for fifteen 10
- minutes. 11
- 12 MR. LAVINE: I think we're covering a lot of ground,
- so it would be helpful to take a break to reorganize anyway. 13
- Q. I want to bring you back to the SDUD data again. Have you 14
- ever used the SDUD data before in your research? 15
- A. I have. In one of the papers listed in my CV, in the 16
- 17 Quarterly Journal of Economics, I use that data with -- it's a
- 18 coauthored paper with Fiona Scott-Morton in 2006 to look at
- 19 pharmaceutical prices in the U.S. and the fraction of --
- 20 THE COURT: Didn't she represent --
- 21 THE WITNESS: Yes.
- 22 THE COURT: -- Schering? She was in the Track One
- 23 trial, I think, right?

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- 24 MR. HENDERSON: She testified at the tutorial.
- 25 THE COURT: She did the tutorial. Yes, I remember

- 1 analysis.
- 2 Q. And the journal it was published in?
- 3 A. The Quarterly Journal of Economics.
- 4 Q. In a peer-reviewed --
- 5 A. Peer-reviewed journal, and it was the lead article in
- 6 February of 2006, so at Page 1 to 31. So that was, you know,
- 7 it is a study that -- and it inspired us to do more work on
- 8 Medicare Part D and other things, but it's a -- the SDUD data
- 9 is great, it's terrific. It's incredibly useful data.
- 10 Q. Can you go back to your Figure 2 of your original report,
- the second page after Tab 1. There's a few different things to 11
- cover. I don't know if we'll get it in in eight minutes, but 12
- 13 just quickly, what is the pink line on here? Because you have
- 14 it identified as an average price. What is that?
- 15 A. That is the average price to the pharmacy classes of trade
- 16 in Abbott's indirect data, transactions that occur through
- 17 wholesalers and distributors.
- 18 Q. And for one particular product?
- A. That's right, for vancomycin, which is actually, at least 19
- 20 in terms of Medicaid spending, by far the largest product of
- 21 the 44.
- 22 Q. And you said it's limited to pharmacy classes of trade?
- 23 A. That's correct.
- 24 Q. Okay, how does that differ from an average for all classes
- 25 of trade?

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- A. So in a subsequent table of the report, I sort of show 1
- THE WITNESS: Right. 2 that, sort of to get a sense of how prices vary across the
 - different classes of trade, an inspection of that data reveals 3
 - 4 that pharmacies tend to pay substantially more than other
 - 5 customers, so about 20 percent more for the retail pharmacy
 - 6 class of trade, for example. There are a few other classes of
 - 7 trade that are included in here, but the big one is the retail
 - 8 pharmacy, and they're about 20 percent more than the average
 - 9 price on average. And so, once again, there will be product
 - 10 quarter combinations where they're less than 20 percent, others
 - 11 where they're more than 20 percent, but on average, they're
 - 12 about 20 percent higher than the all-customer average price.
 - Q. And the averages you used for the pharmacy class of trade, 13
 - did that account for all discounts and rebates that were 14
 - 15 offered by Abbott?
 - 16 A. It did not. It excluded some of them. So if one looks
 - 17 at, for example, Table 7, there's this customer rebate that
 - 18 accounts for about 7 percent, that represents about 7 percent
 - 19 of invoice, and that was not subtracted off in that analysis.
 - 20 So it does not account for every single rebate in the --
 - 21 Q. So were you pointing to --
 - 22 A. Table 7.
 - 23 O. Table 7.
 - 24 A. Yes. So it is...
 - 25 Q. Now, so this is the average price. That's not the price

- her. It's just an unusual first name, if nothing else, so --
- 2
- 3 THE COURT: All right.
- 4 A. So in that study, we set out to estimate the effect of
- 5 Medicaid reimbursement rules on pharmaceutical prices
- 6 generally, and we used the SDU data for that. And that was the
- 7 lead article. The QJE is I think the most highly cited e-con
- journal. Like, for us, that was a great publication. It's
- 9 been a paper that I think has people -- I think people have
- liked it a fair amount. I think it's a pretty highly regarded
- 11 study. It is a well-regarded study.
- 12 It's also interesting because it illustrates in that
- analysis, how did we form our sample? Well, we focused on the 13
- top 200 selling drugs in the U.S., and, coincidentally, those 14
- 200 drugs accounted for about two-thirds of drug spending in 15
- 16 the U.S., and --
- 17 THE COURT: Are they branded or generics?
- 18 THE WITNESS: They're branded drugs. And so it's an
- 19 interesting study because it illustrates both the value of this
- SDUD data and also this notion of focusing on the big, whether 20
- 21 it's in this case drugs in the current setting states, the
- 22 observations that are disproportionately important and trying
- to infer something marketwide. And so it is -- yes, so that's 23 in one example. I've used the data for other work as well, but
- that's certainly the one where it's very at the center of the

14 (Pages 50 to 53)

- you used in your analysis, right? Was that scaled upward?
- A. That's right, so there's kind of two things to think about
- here. Pharmacies pay more on average, so by telescoping in on
- the pharmacy classes of trade, that's going to result in a
- 5 higher price than using the all-customer average price would.
- 6 And then on top of that, I scale it by 25 percent. So what
- that means is that -- let's take a product for which the
- 8 all-customer average price was 5. That 20 percent higher for
- 9 the pharmacy would suggest they're paying about 6 on average,
- 10 and then kick that up another 25 percent brings you to 7 1/2.
- So there will be exceptions, but basically multiplying the 1.2 11
- 12 by 1.25 suggests, you know, in the neighborhood, 40, 45,
- 13 50 percent higher than the all-customer average price is the
- price that I'm utilizing in my Medicaid and Medicare analyses. 14
- 15 Q. And how does that compare, that scaled-up price, the
- 16 pharmacy class of trade excluding some of the impacted
- 17 discounts, the other 25 percent, how does that price compare to
- 18 the overall -- I'm sorry. The price that we're discussing,
- 19 it's the pharmacy class of trade, not including the impact of
- 20 certain discounts and rebates, and then scaled up by
- 25 percent -- can we agree, we'll call that the alternative 21
- 22 prices?

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- A. The alternative AWPs?
- Q. Okay. How does that compare to the overall prices paid by
- Abbott customers?

5 percent are paying that or more. And one of the tables in

- 2 the report that I think is helpful in assessing this is, if one
- 3 looks at Table 13-B behind Tab 1, so this is just seeing how
- 4 does the use of 125 percent of the average pharmacy -- so, your

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5 Honor, do you have it?

6 THE COURT: Yes, I've got it, and then we'll finish 7

this and take our break.

8 THE WITNESS: Okay, so the bottom two lines. So I

9 think it's useful to look at the top line. If I were to use

10 the average price for pharmacies, I get a difference in the

11 state of Illinois of about 12.5 million. If instead I used the

12 all-customer price, average all-customer price, the difference

13 would be about 12.8 million, so higher, reflecting the fact

14 that pharmacies tend to pay more. So when you plug in those

15 higher prices into the Medicaid adjudication algorithm, the

16 difference is lower.

17 Then if we just skip the next line and go to the 18 fourth line, the 95th percentile pharmacy price brings it down

19 from 12.5 to about 11.9. But that's almost identical to

20 125 percent of the average pharmacy, which is on the next line,

12.0. So this is for the state of Illinois. So you can see

22 this is, I think, a useful way to think about -- there are

23 other ways to summarize it just looking at the price data

24 itself, but this is all these prices. So, once again,

25 44 products, 44 quarters, about 2,000 average prices are being

Page 55

1 then used in adjudicating all of these Medicaid claims, about

2 530,000 or 540,000 Medicaid claims; and whether you use the

3 95th percentile or the 125 percent of the average, it's pretty

4 similar.

5 THE COURT: Okay, we'll take our break, fifteen

6 minutes. How much longer do you think you have? We can go off

7 the record on this.

(Discussion off the record.) 8

9 (A recess was taken, 3:30 p.m.)

10 (Discussion off the record.)

11 (Resumed, 3:53 p.m.)

BY MR. LAVINE: 12

13 Q. Dr. Duggan, I wanted to go back to your Figure 2, the one

right after Tab 1. Actually, I'm not sure if this will help or

15 not, but I think the chart will help. Can you describe how you

16 considered the issue of differences between states as to

17 whether the ultimate payment was based on a MAC or a U and C

18 and how that affected your analysis?

19 A. Can you repeat?

20 Q. Sure. The impact of the actual payment as adjudicated by

the state having been based upon a MAC or a U and C as opposed

22 to an AWP --

23 A. Right.

24 Q. -- that was based upon Abbott's inflated list prices, how

25 did that factor into the way you handled it?

A. On average, 40 to 60 percent higher. So 50 percent on

average would be about that amount, maybe even a little bit

3 more than that when one accounts for the discount issue that we

mentioned. So we're 50 to 60 percent. You know, and I haven't 4

5 looked at that distribution recently, but basically one can

6 sort of back-of-the-envelope it here. Pharmacies pay about

7 20 percent more. Rebates are about -- so just the pharmacy and

8 the 25 percent kick goes to 150 percent. And then if one

9 further accounts for the fact that I'm not including certain

rebates, 55, 60. I just don't have -- the hesitation of

adjusting beyond 50, I don't have fresh in my mind how much of

those rebates are pharmacy as a share. So but it would adjust

13 it up still further, so in the neighborhood of 50 percent or

14

15 Q. So by the time you scaled upward, does it match up with

16 any specific percentile of Abbott's sales?

17 A. It's in the neighborhood typically of the 95th percentile,

and it's helpful -- I mean, I think here --18

19 THE COURT: Could you say that in a full sentence.

20 THE WITNESS: So 125 percent of the average pharmacy

21 indirect price is generally in the neighborhood of the

22 95th percentile pharmacy price.

23 THE COURT: 95 percent of its customers are paying 24 that?

25 THE WITNESS: 95 percent are paying that or less;

15 (Pages 54 to 57)

Page 58

 $1\quad A. \ \ \, So \ in terms of the claim-by-claim analyses that I did in$

- 2 these 10 states, I guess the way to think about what the sort
- 3 of how my algorithm calculated this difference in each case, it
- 4 basically took the Abbott transaction price to pharmacies,
- 5 kicked it up by 25 percent, and often, very, very often that
- 6 would obviously fall quite a bit below the published AWP in
- 7 that period.
- 8 Now, there would be times in which the -- let's say the
- 9 state was paying -- a claim was being paid on usual and
- 10 customary, and the usual and customary on a per-unit basis,
- 11 take, like, '98 when the average price was about 5 and the
- 12 published AWP was about 70, all right, so there's a discrepancy
- 13 there of about 64. Suppose that the provider submitted a usual
- 14 and customary of, I don't know, 30 for that product, then the
- 15 difference, instead of being 70 minus 6 would be sort of in the
- 16 neighborhood of 30 minus 6 on a per-unit basis. And to the
- 17 extent that that happened, you know, so -- and similarly for a
- 18 MAC, there might be a MAC in effect of 20 or 30 or 40 for that
- 19 product -- to the extent that that happened, and that happened
- 20 quite commonly in the 10 states for which I had data, and so I
- 21 used the information from many, many, many claims, hundreds of
- 22 thousands of claims for these, you know, almost 2 million
- 23 claims for these 10 states, the frequency with which usual and
- 24 customary was being paid, MAC was being paid and so forth, to
- 25 sort of estimate what the difference would be in these
 - Page 59
 - alternative places. And so I'm not sure if I'm getting at
- 2 exactly what you're asking, but basically --
- THE COURT: Well, does usual and customary vary a lot state by state?
- 5 THE WITNESS: There is a little bit of variation.
- 6 THE COURT: That's what you told me about before.
- 7 THE WITNESS: Right, there's some variation. It's not 8 massive but --
- 9 THE COURT: But that was the 6 percent?
- THE WITNESS: That is driving part of that 6 percent,
- 11 and quite plausibly explaining all of it, that there is a
- 12 little bit of variation from one state to the next in terms of
- 13 usual and customary, and in the aggregate, the 10 look very
- 14 similar to the 38.

1

- THE COURT: And you could do that, if you had the
- state-produced data, you could figure it out more precisely and the second set of data, but not just if you had the SDUD data,
- 18 or whatever you call it.
- 19 THE WITNESS: The SDUD data, right.
- THE COURT: The SDUD data.
- THE WITNESS: The SMRF/MAX you can absolutely do it.
- 22 THE COURT: Right.
- THE WITNESS: The SDUD data, to the extent that it's
- going on, it's going to be reflected in lower amounts paid, so
- 5 it's to some extent --

- THE COURT: You just won't know why?
- THE WITNESS: Right, that's right. Is it a usual and
- 3 customary, or is it some other factor in the SDUD data? But

- 4 that's why I sort of combined the empirical analyses of the
- 5 millions of claims with an examination of the adjudication
- 6 methodology that's used by the various states. And, I mean, if
- 7 there's any part of Medicaid reimbursement, you know, where
- 8 there's -- there's always differences across states because
- 9 there are 50 state Medicaid programs, 51 state Medicaid
- 10 programs the states administer, but the similarity with respect
- 11 to pharmaceutical reimbursement during this time period is very
- 12 high. If I were doing this for nursing home reimbursement or
- 13 the reimbursement of physicians or something else, there is
- 14 more heterogeneity on those mentioned. But in terms of
- pharmaceutical reimbursement, the frequency with which states
- 16 are AWP minus 10 with a dispensing fee, and there are wrinkles
- 17 also to it, but the examination of the methodology indicates
- between the 10 and 38 just a great deal of similarity.
- THE COURT: And do they all have MACs?
- THE WITNESS: Do they all have MACs? For these 44, I
- 21 don't believe so during this period, no. But I don't have that
- 22 particular one at my fingerprints, but I think, as time wore
- 23 on, states became more and more -- there's kind of two things
- 23 on, states became more and more -- there's kind of two things
- 24 going on: Does a state have a MAC program or not? Then how
- 25 many of the -- I think at any point in time, there are 25,000
- Page 61

 1 NDCs being reimbursed by Medicaid. And so whether it applies a
 - 2 MAC to a specific NDC, even if a state has a MAC program in
- 3 effect, that doesn't mean that it does for these products. So
- 4 it is not -- there are certainly some states, to the best of my
- 5 recollection, that do not have MACs for these products during
- 6 the period.
- 7 Q. Well, specifically, what was the impact of the lesser-of
- 8 methodology in connection with this issue?
- 9 A. Right, so the lesser-of methodology, the states are
- 10 similar in the sense that if the formula, AWP minus 10 plus a
- 11 dispensing fee, let's say, generates 60, but the pharmacy
- 12 charges 40, the state is going to pay the lesser of those two
- 13 amounts. And so that's one very important respect in which the
- 14 states are similar on that dimension. So that lesser-of
- 15 methodology is going to result in a lower difference-to-
- 16 spending ratio than would result if it was solely driven by the
- 17 formula. It's going to tend to -- for the claims paid on usual
- 18 and customary, all else equal, they're going to tend to have
- 19 lower paid amounts, and so that's going to be reflected in a
- 20 lower difference. But that's very common. As I said, it's
- 21 about 24 percent of the time usual and customary is being paid
- 22 on these 10 versus about 24 or 25 percent in the remaining 38,
- 23 so it's common.
- Q. But if the alternative price were higher than the basis of
- 25 reimbursement, regardless if it was based on a MAC or a usual

Page 64 Page 62

- and customary, would you have calculated any difference in that 1
- 2
- 3 A. No. So suppose that the usual and customary in that 1998
- example, suppose they had submitted, let's say, for this vanco
- product one unit, an average price of about 5, add that to a
- dispensing fee of, let's say, 5, so that's a \$10 prescription.
- If the pharmacy had charged \$9, zero difference, no difference.
- And in fact there are a decent number of claims for which there
- is no difference, and it's actually more common among those
- 10 claims paid at usual and customary. So if you look at the
- claims that are paid based on the adjudication, like the AWP 11
- 12 minus 5 or 10, those, I mean, not surprisingly looking at this
- 13 figure, if they're basing reimbursement on AWP, it's pretty
- much always -- not always, but it's rare that the difference is 14
- zero, but for usual and customary, it happens a decent amount. 15
- Q. What is Tab 4 in the materials that you have in front of 16
- 17 you?
- 18 A. So this is a summary of the adjudication methodologies
- 19 used by each of the states, and at my direction, Myers &
- Stauffer compiled this information from a variety of sources,
- as indicated in the color-coded bars just below the graph. So 21
- there's a lot of detail here on how states are reimbursing,
- and, you know, one can see that the methodologies do change to
- some extent over time within the states, and that, you know, it
- provides data on -- am I looking at the right thing? -- it

- THE COURT: As AWP goes up. 1
- 2 THE WITNESS: It is my recollection actually, I think,
- 3 that -- so the following statistic would be consistent with
- 4 that, which is to say usual and customary is paid less often
- 5 over time, suggesting that it's going up perhaps even a little
- 6 more. I'm not sure, but certainly I do think that it tended to
- 7 increase over time despite --
 - THE COURT: It's less than AWP but usually more than
- 9 the prices that people pay?
- 10 THE WITNESS: More often than not it's above AWP, what
- 11 they're submitting as the usual and customary, because more
- 12 often than not -- because remember I said that about --
- 13 THE COURT: You would say U and C is usually above
- 14 AWP?

8

- 15 THE WITNESS: It is, in many cases it's above, so
- 16 because it's a lesser-of methodology that's used, and so the
- 17 formula, let's say AWP minus 10 in a particular state, that is
- 18 more often paid than the usual and customary amount. In some
- 19 cases, some states, the provider may not submit it. It's going
- 20 to varv.

1

- 21 THE COURT: So that's consistent, actually, because if
- 22 one is U and C, it's not U and C minus 10 percent.
- 23 THE WITNESS: That's right, that's right. So it could
- 24 be right at AWP, they could be charging exactly AWP, but it
- wouldn't be paid, given that. But, as you can imagine, this

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- provides data on the methodology.
- 2 THE COURT: Do you know how to use this document
- 3 camera?

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9

- 4 MR. LAVINE: No. I have not used this, Judge.
- 5 THE COURT: Robert, will you show them.
- 6 THE CLERK: It's just an overhead projector. Put the
- 7 thing on it. It should be on.
- 8 (Discussion off the record.)
 - THE WITNESS: So this is a detailed description of the
- adjudication methodologies that were in effect in each of the
- states during the time period of interest, telling things like 11
- 12 what is the estimated acquisition cost, what is the standard
- dispensing fee and so forth. And there's many components of 13
- information here, but I made good use of these in carrying out 14
- the analyses that are summarized in my report and in subsequent 15
- 16 rebuttal report and so forth.
- 17 THE COURT: And you are defining usual and customary
- 18 as what, just the bills charged?
- 19 THE WITNESS: Yes, how it's coded in the state data
- 20 varies from one state to the next, but it's essentially the
- 21 pharmacy-charged amount.
- THE COURT: And in other cases, since I have so many 22
- 23 of these, I learned that they tend to track AWP. Would you not 24
- agree with that? In other words --25
 - THE WITNESS: They tend to go up.

- was not something that Myers & Stauffer did in an afternoon.
- 2 This took a considerable amount of research, and they really
- 3 put an enormous amount of work into this. And then I made good
- 4 use of this in the analyses in my report and in comparing and
- 5 sort of assessing the comparability of the initial 10 states
- 6 with the remaining 38.
- 7 So, for example, I believe the frequency with which
- the first 10 used AWP for most of the period, I think eight of
- 9 the ten used AWP for most of the period, and 30 of the
- 10 remaining 38 used AWP for most of the period, and it's like the
- 11 exact same ratio, 80 percent in both cases. So that's an
- 12 example of the kind of thing that I was able to gauge the
- comparability of looking across these two different -- across 13
- 14 these methodologies.
- 15 MR. LAVINE: Your Honor, could we have Attachment 4 marked for identification, please.
- 16 17 THE COURT: Why don't we have this whole binder marked
- 18 for identification.
- 19 MR. LAVINE: Oh, I'm sorry, sure, the whole binder. I
- 20 misinterpreted my colleague's request.
- 21 THE COURT: It's not been filed separately like this,
- 22 has it?
- 23 MR. LAVINE: No. No, the Exhibit 4 was filed as part
- 24 of our summary judgment exhibit.
- 25 THE COURT: Yes, I have a crate upstairs, so let's

- just put this in a succinct form, and we'll mark it 1 for 1
- 2 Identification.
- 3 (Exhibit 1 marked for identification.)
- 4 THE COURT: All right, let's just pick up speed here,
- 5 even though I know I've been the one slowing you down.
- 6 Q. So at some point you concluded that the 10 states were
- sufficient. How did you decide that they were enough?
- 8 A. That the 10 states --
- 9 Q. What types of things did you consider? How did you get to
- that point? 10
- A. Well, there are a number of things that I considered, so 11
- 12 these adjudication methodologies, that's one of the things that
- I considered in assessing this. And, additionally, that 13
- 14 comparison of the average paid amount per claim between the two
- 15 sets of states suggests that they are quite comparable.
- 16 Additionally, I think it's worth noting that the analyses
- 17 that I do take into account -- so states are going to differ
- 18 with respect to which of the 44 products they're reimbursing
- 19 for, and so the analysis takes that into account by looking
- 20 within each of these NDC quarter combinations 2,000 different
- NDC quarter combinations, accounting for the fact that it just 21
- may be the case that Vermont doesn't use much vanco, whereas
- 23 New Hampshire uses a very large share of vanco, like, it
- 24 accounts for a disproportionate share.
- 25 So not only did I do a number of things to assess the

economists get data for one firm or a number of firms, or, you 1

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- 2 know, it's one state or a multiple small number of states, so
- 3 it is quite common to use nonrandom samples.
- 4 Q. You're referring to the study entitled "How Much
- 5 Uncompensated Care Do Doctors Provide"?
- 6 A. That's right, that's right.
- 7 Q. What was the basis of the sample that was used in that
- case? Do you remember?
- 9 A. So the sample, I think in the U.S. there's on the order of
- 10 about 600,000 physicians, plus or minus, depending on how you
- 11 count them. I think that's -- maybe four -- I don't know, it's
- 12 a large number. In their sample they had about 4,000
- 13 physicians, and these were physicians that contracted with a
- 14 particular claims processing company, and so they were using
- 15 data for a very small share of all physicians to leverage that
- 16 to say something about physicians in the U.S. as a whole.
- 17 And, moreover, they didn't have -- in this project, this
- 18 report, I have an incredible amount of data for this group to
- 19 which I am extrapolating. I have the CMS SMRF/MAX data, the
- 20 CMS SDUD data. That is much more than people typically have
- 21 when extrapolating to a larger population. So in terms of
- 22 the -- I mean, it's a much smaller sample. In fact, their
- 23 sample looks much different from the larger population than my
- 24 sample does.

24

for?

25 And I think it's fruitful in thinking about this, one can

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- comparability of the adjudication methodologies, the paid 1
- 2 amounts that resulted and so forth, but similarly, to the
- 3 extent that there were differences in terms of the pattern
- across products or the pattern over time, I'm accounting for 4
- 5 that because there is definitely heterogeneity on that front.
- And that's what makes this CMS data so valuable is that I'm 6
- 7 not -- you know, I'm basically taking into account these 2,000
- 8 different sets of heterogeneity, which is, you know, it's a
- 9 standard thing that is done to adjust for any differences
- between a sample and the larger population. That's exactly the 10
- 11 kind of thing I'm doing. So to the extent they differ, I'm 12 accounting for that with this methodology, but broadly the
- 13
- methodologies are quite similar.
- Q. Is it common to use nonrandom samples in your field? 14
- A. Definitely, and while doing it, to take care, if one wants 15
- 16 to infer more about the larger population, to take care that,
- 17 you know, it's sort of a fundamental issue: Is the sample at
- 18 hand representative of the larger population? And to the
- 19 extent that it isn't perfectly representative, you know, there
- 20 are standard adjustments. That Gruber-Rodriguez paper that I
- 21 talked about at the outset, for example, they take account of
- 22 the fact that in their sample they have relatively many from
- 23 California and relatively few in small practices and so forth,
- and adjust accordingly to say something about the U.S. as a 24
- whole. And again and again people are getting, you know,

- say, well, it's 10 states; but it's 10 states, it's 44 products 1
- 2 and 44 quarters. So at some level, you know, it's up to 20,000
- 3 different state NDC quarter combinations with many claims
- 4 underlying them, so a lot of information there.
- 5 Q. Well, could you have used a random sample in this case?
- 6 A. So it would have been theoretically possible, but one of
- 7 the constraints here was the issue of certain states did not
- 8 produce data. So I think maybe it's Oregon they did not
- 9 produce data. And so if I had randomly sampled from those
- 3 million claims and an Oregon claim had come up, I would not
- 11 have been able to use that from the state-produced data.
- 12 And similarly, the sort of issue here, there's an enormous
- 13 fixed cost associated with mastering the data sets, the
- 14 Medicaid data sets, because each state differs with respect to
- 15 how they code the claims. And so doing each additional state
- 16 takes an enormous amount of work. And part of what as an
- 17 economist -- you know, as a trained empirical economist, I've
- 18 done work with a lot of large-scale data sets -- one has to
- 19 determine where do you draw the line because one could be
- 20 engaged in the process of data collection ad infinitum. We can
- 21 always get more data somehow with so many applications.
- 22 THE COURT: How much would it cost to do each one of 23 the remaining states that we have the claims-by-claims data
- 25 THE WITNESS: Well, we've done now 9 of them, and

- these are the 9 that we have the most data for. And so of the 1
- 2 remaining, I think like Hawaii, we may have one year of data
- 3 for Hawaii, so we didn't pay the fixed cost of -- but, you
- know, it certainly would be possible. It's going to depend.
- Some states are really straightforward, so you get the data and
- it's a -- it varies a little bit from one state to the next.
- but I don't have a good sense right now of the time. But, I
- 8 mean, part of the reason we went to considerable lengths to
- 9 sort of -- you know, there was this claim that the
- extrapolation methodology was not valid, so we subjected it. 10
- We said, all right, I'm going to do this analysis to get that 11
- 12 state, download that state-level data and do that analysis and
- 13 subject the data --
- 14 THE COURT: So if you add in the extra 9 states from
- the 10, how many claims did you evaluate? I know there were 15
- 16 2 million for the first 10.
- 17 THE WITNESS: Right. So we're talking about. . .
- 18 Let's see, let me go back to where -- I'll try to do this.
- 19 In Pennsylvania alone is another, that's 50,000
- claims; Texas is another 60,000 claims; Virginia is another 2.0
- 60,000 claims. So right there, that's 121-70 right there. 21
- Connecticut is another 35,000 claims, so 205. Massachusetts is
- 23 another 39,000, so 245. Maryland is another 70,000, so over
- 24 300,000. So over 300,000 claims, and then Minnesota, Iowa, and
- Utah, between 300,000 and 400,000.
- Page 71
- THE COURT: So that's 2.4, and then you would subtract 1
- 2 those from the ones -- so remaining would be in the vicinity of
- 3 400 and --
- 4 THE WITNESS: No, I think remaining would be -- let's
- 5 say, of the remaining, so in Table 25, 900,000. Let's say
- 6 there's 350 in the sample of 9 states, 350,000, so remaining,
- 7 maybe 550 claims for the remaining --
- 8 THE COURT: That hadn't been analyzed to 2.4 that had
- 9 basically?
- 10 THE WITNESS: Yes. So it is -- yes, that's right.
- Q. I just want to touch on one last Medicaid issue. On the 11
- 12 intrastate extrapolations where you take from one year to
- earlier years in that same state, can you just quickly walk 13
- through that, maybe using Michigan where you had five quarters' 14
- 15 worth of data?
- 16 A. Right, so this is the case in which -- I'll just go
- through it quickly because we did it a little bit. Basically, 17
- for each of the 44 products, in Michigan, for example, I would 18
- 19 take the difference-to-spending ratio for each product in that
- 20 first quarter, 2000 quarter four, and then project it
- 21 backwards, but scaling it only down, only down to account for
- 22 the fact that the spreads tended to grow over time. So that
- 23 70 percent ratio for a vancomycin product, let's say, in 2000
- quarter four, it's going to just walk down to probably
- 40 percent by the beginning of the period because the spreads

- 1 then were, instead of like 15 to 1, were more like 8 to 1. So
- 2 it's going to cut it roughly in half, the --
- 3 Q. And moving backwards, did you utilize the Myers &
- 4 Stauffer's methodology summaries that we talked about on
- Exhibit 4, and did you look at the SDUD and the SMRF/MAX data 5

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- to see if it was comparable, things like that?
- 7 A. Absolutely, so I sort of inspected whether and to what
- extent, looking back in time, it was appropriate to deploy, you
- 9 know, to use this ratio. And, you know, once again, it's
- 10 possible there's an example here and an example there, but
- 11 across the board, the methodologies -- I mean, the neat thing
- 12 about using those state-specific NDC quarter combinations is
- 13 that those are going to be the same pharmacies being reimbursed
- 14 in those earlier periods. So it's a useful, but I certainly
- 15 did probe that issue.
- 16 Q. Just to try to cover the rest of the issues, let's switch
- 17 to Medicare. You did two types of extrapolations there, right?
- 18 A. Correct.
- 19 Q. Was all the Medicare data that you utilized claim-by-claim
- 20
- 21 A. Yes. In terms of information on spending and number of
- 22 claims, I combined it with array information, data on arrays.
- 23 But there was only one data set. There wasn't a state-produced
- 24 SMRF/MAX/STUD analog. It's just the Medicare claims data.
- 25 Q. And that is claim-by-claim data?

- 1 A. Correct.
- Q. Okay, no aggregate data there?
- 3 A. Right.
- 4 Q. So the issue for the extrapolation related to the arrays
- 5 on the Medicare side?
- 6 A. I guess I would -- I mean, I would just say that there are
- two types of Medicare claims before going to the extrapolation. 7
- 8 One type are the DME claims for which I'm not doing an
- 9 extrapolation. I'm using --
- 10 THE COURT: Durable medical equipment?
- 11 THE WITNESS: Right, durable medical equipment, that's
- 12 right.
- 13 THE COURT: You're not doing that?
- 14 THE WITNESS: No, no, I'm using those claims, but I
- 15 have arrays that cover the period. There's another set of
- 16 Medicare claims, the Part B claims, the carrier claims, for
- 17 which I am doing some extrapolation. Those claims are
- 18 summarized in Table 34. But I do think, your Honor, I think
- 19 it's helpful to look at Table 34 for a moment.
- 20 THE COURT: Table 34 is?
- 21 THE WITNESS: It's behind Tab 1, and it's the summary
- 22 of Medicare carrier claims. Okay, so do you have that in front
- 23 of you?
- 24 THE COURT: Yes. Why don't you put it up on the
- 25 document camera. We're going to make you high-tech by the end

19 (Pages 70 to 73)

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Page 74

1 of this hearing.

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2 MR. LAVINE: My office is going to make fun of me because I'm supposed to be the high-tech guy.

THE WITNESS: This table is, I think, helpful just getting a big picture on the Medicare data. So \$185 million in 5 Medicare spending during this eleven-year period on the -- I 6 7 think it's eleven J-Codes that are listed in the complaint. Okay, so right off the bat, one thing worth noting is that I examined five of the eleven products, which are the first four, 70-50, 70-40, 70-30. 10

THE COURT: Where are you looking? 11

12 THE WITNESS: I'm sorry. The leftmost column of

13 Table 34. Okay, so they're listed there. This table --

THE COURT: Oh, you're reading the J-Codes.

THE WITNESS: That's right, the J-Codes. So this basically tells you that almost \$100 million in the spending was for J 70-50 and about \$26 million for J 70-40, and so forth

18 down the line.

And so I restrict attention only to the top four and 20 to J 33-70. The top four is sodium chloride, the J 33-70 is a vanco product, and essentially difference equal to zero for the 21 other six. So even before getting into extrapolation, it's worth noting that those six products, once again, it's sort of

drawing the line, time limitation type of thing. Assembling the arrays from the carrier documents and so forth takes an

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1 THE COURT: And J-Code is when you have therapeutic 2 equivalents, generic?

THE WITNESS: That's right, that's right. And basically the way these arrays work is, and, you know, there are inevitably little exceptions here and there, but in general the methodology takes the median of the generic prices --

THE COURT: Of all of them? That's what I couldn't figure out. Of all the equivalent generics?

THE WITNESS: Well, there's a little bit -- there's

10 some variation across the carriers with respect to which 11 products get included in the arrays. So, you know, one carrier 12 might include -- there's a huge amount of similarity, but when 13 you look at, let's say, the array in '98 for Wisconsin 14 Physician versus Connecticut General, you know, they may both 15 have seven products in their array, and five or six may be the 16 same, but there may be one or two that differ. But it's not 17 necessarily the case that all products are included. In fact, 18 more often than, not all of the equivalent products are 19 included, but a very large number are included.

pick a particular quarter, '97 quarter four. Suppose I have 21 22 the array for J 70-50, and let's say there are five products in 23 that array, two Abbott and three other firms' products. And 24 let's suppose just for simplicity that those prices are 8, 9, 25 10, 11 and 12, with Abbott at 11 and 12. They don't have to.

And so these arrays allow me to determine -- let's

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enormous amount of time, and here I focused on just five of the

eleven products, so the majority of products were excluded.

3 And rather than trying to extrapolate across products, I did

4 not. I could have come up with a difference from these five

5 and extrapolated it to the other six, but recognizing that

6 there's heterogeneity across products and so forth, I didn't.

7 So those claims are ignored in the analysis. The difference is

8 set to zero for them.

> So right off the bat there is, in terms of the total amount of spending, it's more than \$20 million of those \$185 million, so I think it's about \$22 million. So about 12 percent of the spending -- I'm doing this a bit on the fly in my head, but I think about 12 percent of the spending, just I set difference equal to the zero right off the bat. So I just wanted to make that point before going to the discussion

16 of any extrapolation. 17 Q. Can you remind the Court how the arrays came into play in

18 connection with setting the allowed amount for a Medicare

19 claim.

20 A. Sure. So for any of these products, the key distinction

21 between Medicaid and Medicare, if there's one thing to remember

about Medicaid and Medicare, Medicare, instead of paying based

solely on the AWP, let's say, of an Abbott product, for these 23

J-Codes, typically carriers used AWPs for multiple firms'

products and then took the median.

They could be a third, 8 and 9; it won't have any effect on the

1 2 median. Suppose they're the 11 and 12 in that example. So

3 initially with their initial AWP the median is 10.

4 Okay, now suppose that one plugs in the price, that 5 pharmacy, 125 percent that I described earlier in for the 6 Abbott prices, they typically will fall below, often below --

7 in that example would fall below the eight. And so the median

8 would fall from 10 to 8. But it's not a one-for-one change,

9 which is to say, if you lower the AWP from 10 to 5, often with

10 Medicaid reimbursement you essentially cut in half the

11 spending, the (Inaudible) dispensing fee for a second. Here --

THE COURT: Here you're moving down the median.

13 THE WITNESS: You're just moving down the median, but

14 it's affecting all of the claims with that J-Code. So it is

15 a -- right, so basically using arrays, using an enormous amount

16 of array information that was assembled by Myers & Stauffer, I

17 determined how for many of these J-Code quarter carrier

18 combinations, how do alternative, you know, transaction-based

19 AWPs for Abbott products, how do those influence the median,

20 and then run that through the Medicare claims. So you can see

21 here there are 22 million, a lot more Medicare claims than

22 Medicaid claims, 22 million Medicare claims; essentially figure

out for each carrier J-Code quarter combination, what's the 23

24 effect on the median; and then see how claim by claim the paid

25 amount differs between -- you know, when you use that.

1 And in some cases it won't be affected. So, for 2 example, if in that earlier example Abbott had the AWPs of 8 3 and 9, if you lowered their prices, it would have no effect on the median, okay, because it's basically the middle price of the five. And no matter what you do to these two prices, that 5 6 it's not going to move that --

THE COURT: Well, will you always know Abbott -- what if Abbott is not in the array at all?

9 THE WITNESS: Then no effect.

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THE COURT: So how would you know when you're extrapolating whether in any given situation Abbott was in the array and counted?

13 THE WITNESS: Right, so in this case, so initially, 14 analogous to the Medicaid, basically for the carrier J-Code 15 quarter combinations where I have an array, I run the algorithm to figure out what is the difference versus what spending would 16 17 have been. Now let's think about other carriers first, like 18 the Vermonts from that earlier example. So one approach would 19 have been to simply take the averages for each of the J-Codes and apply it to the other, the difference-to-spending ratio; 20 suppose the difference-to-spending ratio was 20 percent for one 21 of the J-Codes, apply that to the carriers for which I do not have an array, the claims for the carriers where I do not have 24 an array. That would have been an approach.

J-Code carrier quarter combinations where I have data, the 1 2 Abbott AWP is the median about 24 percent of the time. About

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Page 81

3 one in four of those cases has an Abbott AWP as the median. 4 Turning to the remaining carriers during a comparable

5 period, for them it's about 16.5 percent, so it's less common. And that indicates to me, given my familiarity with these

6 7 arrays and my work, you know, with this kind of data before,

8 that the intensity with which the remaining carriers are using 9

Abbott AWPs is lower. And so in essence, rather than simply 10 taking the ratio for those initial carriers and applying it to

11 that other group, I see there's a difference between the two,

12 it is not the case that the population in my sample is fully

13 reflective, fully representative of the greater population, and

so I adjust down the numbers accordingly, scaling down 14

15 essentially by two-thirds to account for the fact that the

Abbott AWP is 50 percent more common, more frequently the 16 17 median in the -- feel free to stop me at any point. I'm trying

18

19 THE COURT: It's late in the day, and I'm trying to 20 focus myself.

21 THE WITNESS: So here the earlier case, the Medicaid 22 case, I said, let's look at the 10 versus the 38; and they're 23 really comparable, and it's reflected in this subsequent

24 analysis that I did.

25 THE COURT: Right.

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comparability of my sample and the larger population for

However, in the same way that I probed on the

Medicaid, I do it here as well. And how do I do it? You know,

3 if I don't have the array, what can one do? What I can see,

for each claim, whether the allowed amount is itself an Abbott

5 AWP. So for those J-Code carrier quarter combinations where I

6 have the array, in many instances an Abbott AWP is the median.

7 And so by definition, in those cases, the median moves because

8 when you adjust AWP at all, it always goes down.

THE COURT: But that's when you have the data?

THE WITNESS: That's when you have the data. Now,

12 of claims for other carriers, I can see, well, what about them? How often do they have an Abbott AWP as the median? And so I 13 14 can gauge whether and to what extent. So how often is it the 15 case that an Abbott AWP is the allowed amount in the claim for that carrier in that quarter. 16

but, having the claims data, having these millions and millions

THE COURT: I see. So you might not have the array, but you'll see, bingo. Now, suppose you don't have that.

19 THE WITNESS: No, I do because I basically 20 assembled --

21 THE COURT: So suppose it's not Abbott's AWP.

22 THE WITNESS: Right, and more often than not it's not

Abbott's AWP. And so what I figure out is that for about one 23

24 in four claims in the array, in those -- I hate to keep saying this, but I just want to be as precise as possible -- for those

THE WITNESS: These carriers, the Wisconsin Physicians where I have the data versus the carriers where I don't have

3 the data, it is clear -- and you can imagine there was a

4 considerable amount of work that went into figuring out, is

5 this an Abbott, are these Abbott AWPs or not? And, you know,

6 there are some cases, some example here or there where in the

7 same quarter an Abbott product had the same AWP as another

8 product, but that's going to happen in both data sets. I can

9 tell you from having looked at dozens and dozens of arrays that

10 Abbott AWPs are often the median. And so --

11 THE COURT: You said a quarter of the time, right?

12 THE WITNESS: A quarter of the time, that's right.

13 And so I basically take the results for those initial carriers

14 and scale them -- so rather than taking that difference ratio

15 for the initial group of carriers, I scale it down by

16 approximately a third.

THE COURT: Where did you get that?

18 THE WITNESS: Or a fourth. It's basically it

19 represents the --

THE COURT: Where are we?

21 THE WITNESS: We're in the neighborhood of Page 124 of

22 the report.

17

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THE COURT: That's the first --

24 MR. LAVINE: Tab B.

25 THE COURT: All right.

THE WITNESS: So in Equations 10 and 11 on Page 125,

2 I'm describing here basically how I'm calculating the

- 3 difference for J-Code J and Carrier K over the period of
- 4 interest. So I apologize, I don't want to forget the equation.
- 5 So just the big picture --
- 6 THE COURT: Others are probably more astute right now.
- 7 I'm counting on my law clerk who wasn't sitting through this
- 8 trial this morning. So just in plain English, you've got a
- 9 quarter that are the same.
 - THE WITNESS: Yes.
- 11 THE COURT: So you can extrapolate across the
- 12 carriers

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- 13 THE WITNESS: Right. A quarter in my sample have
- 14 Abbott AWPs. A sixth or less -- I'm getting the numbers
- 15 confused, but less for the other sample. So I've got a sample;
- 16 there's a population. For the other carriers where I don't
- 17 have arrays, they have Abbott AWPs less frequently.
- THE COURT: So it's only a sixth of the ones you don't
- 19 have the data for are actually compensating at what the Abbott
- 20 one is?

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- 21 THE WITNESS: Exactly. And I should note that for
- 22 every time that an Abbott AWP is the median, there are more
- 23 than two where they're above the median and affected. Do you
- 24 see? So it's not like by knowing -- it's not like only in one
- 25 in four cases is Abbott affecting the median. There are a heck
 - Page 83
 - of a lot of cases where they're above the median, but this is
- 2 just a measure of the intensity.
- 3 THE COURT: So a sixth don't -- only a sixth are AWP
- 4 of the other --
- 5 THE WITNESS: Of Abbott, yes.
- 6 THE COURT: Of the other five-sixths, how do you
- 7 figure out whether Abbott matters?
- 8 THE WITNESS: Right, so the assumption, the
- 9 identifying assumption here is that the pattern that holds
- 10 within the arrays for which I have information, so for every
- one time -- I don't have this number right here in my head, but
- 12 suppose that for every one time that an Abbott AWP is the
- 13 allowed amount, there are two where they -- two different
- 14 claims where they're not the allowed amount, but they affect -
- 15 but affect -- changing their AWP affects the reimbursement
- 16 amount.
- THE COURT: They're higher than the array.
- THE WITNESS: They're higher than the median, right.
- THE COURT: So you're just assuming that that's gong
- 20 to be the same --
- 21 THE WITNESS: That pattern holds for the remaining --
- THE COURT: That the pattern holds. And how do you
- 23 test that to see if it's true?
- MR. LAVINE: Can I just slip in one question?
- 25 MR. DALY: No.

- 1 MR. LAVINE: It will help.
- 2 Q. Where you did have the arrays, how often was there an
- 3 Abbott product, an Abbott AWP?
- 4 A. The vast, vast majority of the cases when, for these
- 5 sodium chloride and these vanco J-Codes, when there is an
- 6 array, an Abbott product is in there, so the vast, vast
- 7 majority of cases. And it is true, I mean, one can see from an
- 8 examination of -- if one looks at Table 43, so this is also
- 9 after Tab 1 --
- 10 Q. The next-to-the-last exhibit for that tab.
- 11 THE COURT: All right.
- 12 A. So for Connecticut General, you see the first line there
- 13 summarizes the results of the analyses for the J-Code quarters
- 14 where I have array information. I have data for the whole
- 15 eleven years, but for Connecticut General, there are about
- 16 540,000 claims in that last five-year period in which
- 17 the -- 540,000 claims, okay, for the five J-Codes that I'm
- 18 considering that are listed in the title of the table.
- Now, of those, if you look one column to the left, you see
- 20 about 470,000 claims in which paid amount would fall if
- 21 Abbott's AWPs were replaced by 125 percent of the average
- 22 pharmacy. So that's 86 percent of claims where there's
- 23 differences greater than zero, okay.
- Now, going back to that 24 percent, now, remember, the 24
- 25 isn't Connecticut General specific, but suppose it was. So

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- 1 24 percent of the time Abbott's AWP is the median, okay; and in
- 2 essentially all of those 24 percent of cases, moving their AWP
- 3 is going to lower the allowed amount because the AWP always
- 4 falls when you use the transaction-based price.
- 5 THE COURT: So you extrapolated that percentage.
- 6 THE WITNESS: Exactly. So basically I say 24, and
- 7 let's say there's another 62 percent, so that's about two and a
- 8 half claims where Abbott is above the median but not the median
- 9 for every one. And the methodology, basically the assumption
- 10 underlying the methodology is that that pattern holds in the
- 11 remaining carriers, and it is --
- 12 THE COURT: How did you test that? Like, you could
- 13 test the last one.
- 14 THE WITNESS: This, for example, with pulling in this
- 15 new Medicaid data, it is --
- 16 THE COURT: How do you know if that's right, there are
- 17 consistent patterns across the carriers?
- THE WITNESS: Well, it is worth noting that the
- 19 carriers are basically operating under the same CMS guidelines
- 20 throughout this period, and it is true there's variation across
- 21 the carriers.
- 22 THE COURT: There was some OIG report that talked
- 23 about it, right? Or was that in a different context?
- THE WITNESS: It may have been. Yes, maybe my mind is
- 25 getting tired now too.

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- 1 MR. LAVINE: That was a Medicaid issue.
- 2 THE COURT: That was Medicaid?
- 3 THE WITNESS: So the identifying assumption of this
- 4 methodology is -- now, it's worth noting that this isn't
- 5 information for just four or five carriers. This is
- 6 information for -- actually, as you can see here listed, there
- 7 are several.
- 8 THE COURT: So you average the pattern?
- 9 THE WITNESS: Yes, I averaged the pattern across the
- time periods because it bounces around a fair amount from one 10
- period to the next. Things bounce with the Medicare somewhat 11
- 12 more than with the Medicaid where it's all driven by the Abbott
- 13 AWP. So essentially the methodology aggregates the information
- 14 from dozens of arrays. Now, it does it product by product, so
- 15 J-Code by J-Code, but it aggregates the information because,
- 16 for example, vanco tends to have a bigger difference because
- 17 its disparity from the other ones tends to be larger than for
- 18 sodium chloride. So it basically aggregates that information
- 19 across many, many arrays, and essentially aggregates the
- information across those many, many arrays and uses, leverages
- all the information -- in the case of Connecticut General, 21
- 540,000 claims, a million claims for Wisconsin physician and so
- 23 forth -- to estimate for the remaining claims.
- 24 Now, I should also note that in doing this, recall,
- 25 there are a whole number of things that I'm excluding from

listed in both the -- maybe that's the 7th line and the 8th

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- 2 line. So there are some of the carrier numbers, like one
- 3 carrier, the Connecticut General arrays are used for
- 4 Carrier 54-40, for Carrier 55-35, and so forth. So this
- 5 overstates -- if you think about -- it depends on -- think
- 6 about the carriers in terms of their numbers, if this is the
- 7 right figure, if you think about it in terms of --

THE COURT: So if in any quarter you had too few

carriers that you had data for, did you say, "I don't have 9

enough to know a pattern"? 10

11 THE WITNESS: So it's certainly true that I dropped 12 claims where the data did not suggest it would be appropriate

- 13
- to extrapolate, so certainly for those six J-Codes we talked
- 14 about, but also extrapolating back in time, I -- so if we go
- 15 back to the Table 43, you'll see that, for example, for
- 16 Connecticut General, I only went back to early '95 because my
- 17 scrutiny of the data for Connecticut General in the first four
- 18 years of the period suggested to me -- I didn't see enough
- 19 Abbott AWPs then, so I didn't extrapolate back during that
- 20 period. And similarly, for those remaining carriers, I ignored
- 21 the first part of the data set because, once again, the Abbott
- 22 AWPs were less common in '91, '92 and so forth because I don't
- 23 have arrays in '91 and '92.
- 24 THE COURT: It sounds like you're making far more
- 25 subjective judgments with respect the arrays than you really

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- this. For example, those six J-Codes initially, I don't
- 2 extrapolate to them.
- 3 THE COURT: How many carriers did you have full data
- 4 for?

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- 5 THE WITNESS: Full data for? Well, for the entire
- 6 eleven-year period?
- 7 THE COURT: I guess I asked that incorrectly. So
- 8 let's assume -- how many carriers are there all together?
- 9 THE WITNESS: There are -- well, it depends to some
- extent on how you count them because there are multiple -- if
- you go back -- and I apologize for continuing to push your 11
- Honor from one table to another, but -- so if one goes to 12
- Table 35, this provides information. And do you have 13
- highlighted in yellow? 14
- 15 THE COURT: Yes.
- 16 THE WITNESS: So highlighted in yellow are the
- 17 carriers for which I have array information, and in white are
- 18 the ones for which I do not have array information.
- 19 THE COURT: So you probably have slightly less than
- 20 half?
- 21 THE WITNESS: Slightly less than half, that's right,
- in terms of -- I'm just going to go to -- slightly less than 22
- half, that's right. 23
- Q. Are some of the carriers listed multiple times?
- A. That's right. So Connecticut General you can see is

- would of the Medicaid. In other words, what's enough to be a 1
- 2 pattern, what isn't? Do I have enough data, don't I? And
- 3 there's no way to test it.
 - THE WITNESS: Well, I think it's useful to sort of see
- 5 how the difference-to-spending ratio differs between my sample
- 6 and the population to which I'm extrapolating. So, first, in
- 7 terms of the across-carrier extrapolation, so for those carrier
- J-Code quarter combinations where I have the array, if one
- 9 looks there, the ratio of difference to spending is about
- 10 29 percent. Okay, it's lower than for Medicaid because of this
- 11 thing we were talking about that went -- the median doesn't
- 12 move as much as the AWP moves. So about 29 percent.
- 13 For those carriers to which I'm extrapolating, it's
- 14 less than half that amount, so it's like 14 percent because I'm
- 15 accounting -- I'm sort of scaling down by even more than our
- 16 discussion a little while ago suggested to account for this
- 17 difference in the data.
- 18 THE COURT: So if you have, guesstimate here, a
- 19 hundred carriers here?
- 20 THE WITNESS: Ninety, I think there are.
- 21 THE COURT: Ninety, all right, ninety. If you had
- eighty carriers, you'd be able to see a pattern and 22
- 23 extrapolate. But what if you only had five carrier arrays?
- 24 Did you just sort of say, "I can't do that"? Am I understanding
- 25 this wrong?

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1 THE WITNESS: No, no, you're understanding it 2 correctly. So I am essentially in this case aggregating 3 information from multiple arrays for the same carrier. So the carriers definitely change. So Wisconsin Physician moved from 5 having five products to seven products, added in new products,

so they're changing all the time. So just as with Medicaid, 6

the notion that it's 10 states only, that's not the way that I 8 would phrase it because these arrays are constantly -- are

9 being updated quite a lot over the time period. So the

10 information that is included in the arrays, there's a lot of --

there are many, many arrays. I don't have the number off the 11

12 top of my head here, but there are dozens and dozens of arrays

13 that I'm using to calculate this difference-to-spending ratio.

And, you know, like I said, there's big variation within a 14 15

carrier. And then I'm using the information for those arrays

16 to extrapolate to this other group, which I recognize is, you

17 know, having drilled down on it, they are somewhat different.

18 And so this is, it's a harder -- I'll concede it's a harder

19 exercise just because of the specifics of it. We're talking

20 about arrays and so forth. But the carriers were all operating

under sort of similar guidelines; and to the extent that they 21

do differ somewhat, I'm really penalizing, I'm really cutting

down that difference-to-spending ratio, whereas with

24 Medicaid --

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THE COURT: Is there any evidence that CMS actually

you know, I will admit this is a hard -- this is not --1

THE COURT: This is a harder nut.

THE WITNESS: This is a harder nut to crack.

4 THE COURT: So if I were concerned about the whole 5 thing you did, would at least the one quarter that are Abbott

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6 that are right at the median, would that be a subset that you 7

felt confident with?

THE WITNESS: Absolutely, I mean, I think that at some

9 level it seems plausible -- so I think it's 1.3 million

10 claims in this other group of carriers that have an Abbott AWP

11 as the allowed amount. And I'm sure that one can find an

12 example where in one of those NDC quarter combinations, both

13 Abbott and Baxter had 10.03, like, there's a little bit of

14 that, but it's certainly not the dominant thing going on,

15 having looked myself at these arrays. But, absolutely, those

16 are -- it is clear what's going on.

17 THE COURT: So for the one quarter where Abbott's was 18 right at the J-Code, you would say it was an extremely accurate 19 methodology, I think. With the others, you're saying you're

20 doing the best you can, the most conservative you can with the

21 data you have?

22 THE WITNESS: Absolutely. And it is my professional

23 judgment that if I had perfect array data for all eleven

24 products for all of these carriers over this entire period, the

25 difference that would emerge from that analysis with perfect

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went and surveyed and regulated the carriers? You say they're

all under the CMS, and my impression from other litigation --2

3 I've been doing this now for a decade -- is that CMS actually

4 didn't do very much to survey the carriers, right? I mean,

5 they may have kept track of the data, but they weren't policing

6 them. Is that wrong? Do we have evidence to the contrary?

THE WITNESS: That's probably not my best --

THE COURT: All right. But I'm just saying, you keep saying they were supervised by the same group. They were like lone wolves, weren't they, each one doing their own thing?

THE WITNESS: Well, I think that there's some sense in

12 which carriers look to one another to some extent.

THE COURT: Well, do you have evidence of that?

14 THE WITNESS: There are some cases where certain carriers that I analyzed eventually piggybacked on Wisconsin 15

16 Physician Services, for example, so there is some evidence of

17 this. But I will concede, there's no question, this was a

18 harder exercise. And because of the -- I mean, I tried through

19 a number of channels to be very conservative here; drop six

20 products from the analysis, don't go back in time all the way 21 to 1991 because there's not enough Abbott products, you know,

22 really scale down the difference going from my sample to the

other group because it's clear that the Abbott AWP is being 23

used less frequently there. And this, in my professional

judgment, using all of my experience as an economist -- and,

1 data would be considerably higher than the one that is 2 resulting here.

3 THE COURT: You mean more adverse to Abbott?

4 THE WITNESS: More adverse to Abbott, that's right.

5 I'm sure there are cases where maybe if we pulled out data for

6 North Carolina Blue Shield and we just happened to have their

7 array, in the same way that some states are a little above the

8 extrapolation, some states are below, sure, that would be true.

But in general, the combination of dropping six J-Codes from 10 the analysis, dropping big chunks of the time period from the

11 analysis, scaling down when going from the sample to the other

group -- and this is, you know, really, I mean, this was a

13 hard -- this was something that I kind of warmed up on. This

14 is a hard part of the analysis, but it is, in my judgment, this

15 number, if I had perfect data, that difference would be

16 considerably larger.

17 Q. Dr. Duggan, what are all the dashes on Tables 43 and 44?

18 I'm not sure that's been clearly described.

19 A. The dashes on 43 and 44 represent those carrier time

20 period combinations that I just drop. So, for example, for

21 Connecticut General on that third line, you can see that I'm

22 only going back in time to the first 130,000 claims. I ignore

23 the preceding 190,000 claims because, as I mention in the

report, the frequency with which they're using the Abbott AWPs

in that earlier period is much lower. So I'm zeroing out

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- 1 there, I'm zeroing out at many other periods within carriers,
- 2 so in a sense penalizing more -- it's a little bit analogous to
- 3 the sort of Medicaid accounting for the fact that the spreads
- 4 were narrower at the beginning of the period, but I'm
- 5 penalizing more aggressively with this Medicare analysis than
- 6 there.

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- 7 THE COURT: Thank you. Now, are you almost done
- 8 because I'd like to finish him today, and then we'll go
- 9 tomorrow?
 - MR. LAVINE: Yes, very close to done, Judge.
- 11 THE COURT: So three minutes, done.
- 12 Q. Did you test your Medicare methodology and extrapolation?
- 13 A. I mean, this one is a harder one to -- it's a more
- 14 difficult one to test, admittedly, because I don't have the
- 15 North Dakota Blue Shield, I don't have those arrays, and there
- would be more variability for this case than the others.
- THE COURT: Have you tried to get those, the arrays?
- 18 THE WITNESS: Basically my understanding is that all
- 19 of the arrays that could be obtained were obtained, and that,
- 20 you know, I guess in the same way one could think, you know,
- 21 maybe it's a draw-the-line kind of thing, so I didn't go to
- 22 some of those other products and so forth, but my understanding
- 23 is that the arrays that could be obtained, given the -- I mean,
- 24 this was an enormous amount of work to assemble these arrays
- 25 for all these products -- is that I got what was available.

- 1 carriers, but pretty close. And to the extent that they were
- 2 lower, that would lead to a lower difference as well, given my

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- 3 methodology.
- 4 Q. But that issue, that was something you considered?
- 5 Q. Absolutely, absolutely.
- 6 THE COURT: Are you finished?
 - MR. LAVINE: One wrap-up question?
- 8 THE COURT: Absolutely.
- 9 Q. Can you describe and explain your level of confidence that
- 10 the work that you performed in this case and the opinions you
- 11 reached are to a reasonable degree of economic certainty.
- 12 What's the level of your confidence?
- 13 A. I, you know, having worked incredibly hard in deploying,
- 14 like, all the skills that I've acquired over graduate school
- and my ten years as a professor, it is my judgment that the
- 16 estimates that I've come up with are incredibly reliable, are
- 17 very, very reliable. And I feel, you know, that to the extent
- 18 that the available data permitted or the available time
- 19 permitted, I probed the validity of these analyses; you know,
- 20 the within-state extrapolation, the across-state extrapolation,
- 21 the within-carrier extrapolation. I'll concede the
- 22 across-carrier extrapolation is a little tougher, but, still, I
- 23 feel very confident that were perfect data assembled with
- 24 infinite time, that the difference, that the aggregate
- 25 difference would be higher. But, you know, I've tried to

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- But I do sort of use the methodology within these carriers to
- 2 try to see, you know, if I pretend the data starts somewhat
- 3 later and so forth, do I get similar results? And the results
- 4 in the aggregate are similar, you know, I'll concede that it's
- 5 not as -- it would be -- it's a -- but, yes, I did probe it to
- 6 the extent that the available data permitted.
- 7 And I should note, the data that are available, this
- 8 is an incredible amount of data, claim-by-claim data for all
- 9 22 million claims during this eleven-year time period of
- 10 interest, and, you know, to having drilled down to this data to
- 11 a great extent to try to come up with the most accurate
- 12 estimate as possible, and where it looked like this
- 13 extrapolation was not appropriate across products, earlier
- 14 periods and so forth, I just didn't do it. I just zeroed it
- 15 out.

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- 16 THE COURT: Thank you.
- 17 Q. So on average, did you examine the difference between the
- 18 allowed amounts in the Medicare claims where you matched them
- 19 to arrays as compared to where you did not match them?
- 20 A. Yes, and in general the two were similar. You know, they
- 21 weren't identical, but they were qualitatively similar. It's
- 22 not like the remaining carriers were reimbursing at 350 while
- 23 the carriers for which I had data were reimbursing at 10. You
- 24 know, there were some -- it was comparable to somewhat -- I
 - 5 think the allowed amounts were somewhat lower for the remaining 25

- 1 telescope in on the most accurate estimate possible, and, when
- 2 there were forks in the road, taken a conservative approach.
- 3 So I feel really very good about the precision of this. I
- 4 would have liked the 6 percent to be 0 percent, but other than
- 5 that, I feel pretty good.
- 6 THE COURT: Thank you. So we all need a break here.
- 7 Tomorrow, now, what time is the Schering-Plough?
- 8 THE CLERK: Three.
- 9 THE COURT: Three o'clock, so I don't think that's
- 10 going to take that long, but I may be wrong. So we're going to
- 11 go from 2:00 to 3:00. We'll take a break for a possible
- 12 settlement. And I think, Department of Justice, are any of you
- 13 involved in that?
- MR. HENDERSON: The Department of Justice will be here
- 15 for the settlement hearing.
- 16 THE COURT: How long will that take? Are there
- 17 objections?
- MR. HENDERSON: Not that I know of, but I don't know.
- THE COURT: If there are no objections, it will be
- 20 very fast. If there are objections, it could be, let's say,
- 21 half an hour, but otherwise you have the rest of the afternoon.
- 22 If we don't finish, it's very important and very difficult --
- 23 we'll finish at least you tomorrow so you can leave. And your
- experts, do you want to have -- I know it's very expensive -- do you want them here no matter what?
 - 25 (Pages 94 to 97)

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Page 100
                                                       Page 98
         MR. DALY: Your Honor, if we're going just 2:00 to
1
                                                                    1
                                                                                    CERTIFICATE
                                                                    2
2
    5:00 with an indeterminate break in there, I'm thinking I may
                                                                    3
3
    want to release them.
                                                                        UNITED STATES DISTRICT COURT)
4
         THE COURT: What?
                                                                    4
                                                                        DISTRICT OF MASSACHUSETTS ) ss.
5
         MR. DALY: I may want to release them for tomorrow on
                                                                        CITY OF BOSTON
6
    the ground that I think, if we have essentially two hours
                                                                    5
7
    tomorrow, I think it will take me two hours to --
                                                                    6
                                                                    7
                                                                              I, Lee A. Marzilli, Official Federal Court Reporter,
8
         THE COURT: I'm thinking it's very important.
                                                                    8
                                                                        do hereby certify that the foregoing transcript, Pages 1
9
         MR. DALY: Yes.
                                                                    9
                                                                        through 99 inclusive, was recorded by me stenographically at
10
         THE COURT: And I don't know how you thought we were
                                                                        the time and place aforesaid in Civil Action No. 01-12257-PBS,
    going to squeeze in spoliation and the motion for summary
11
                                                                        In Re: Pharmaceutical Industry Average Wholesale Price
12
    judgment. Either you're the most optimistic people in America
                                                                   12
                                                                        Litigation, and thereafter by me reduced to typewriting and is
13
    or I should be complimented that you thought I understood this
                                                                   13
                                                                        a true and accurate record of the proceedings.
                                                                   14
                                                                              In witness whereof I have hereunto set my hand this
14
    already. This has been unbelievably helpful today, and I thank
                                                                   15
                                                                        7th day of January, 2010.
15
    you. I'm sure tomorrow I'll learn more, but maybe if you
                                                                   16
16
    wanted to keep one expert around, there should be some time for
                                                                   17
17
    it. I think the Department of Justice should know, right,
                                                                   18
18
    whether or not there are going to be objections from New York
                                                                   19
19
    and Massachusetts? At this point you should know.
                                                                   20
                                                                                 /s/ Lee A. Marzilli
20
         MR. HENDERSON: I think we should. The last
                                                                   21
                                                                                LEE A. MARZILLI, CRR
    communication I heard, your Honor, there was still a little
21
                                                                                 OFFICIAL FEDERAL COURT REPORTER
    uncertainty about it. We didn't have a final communication
                                                                    22
23
    from the states. I'm a little on the sidelines, so I don't
                                                                   23
24
    know the details, but we think there are no objections.
                                                                   24
25
         THE COURT: Well, could you e-mail Mr. Alba and let us
                                                                   25
    know and let them know because, truthfully, if you have two
1
    hours, then there will be some re -- I mean, I think, as a
3
    practical matter, at most we'd hit one expert, even without --
4
    even if I had only --
5
          MR. DALY: I think at most, Judge, I agree.
6
          THE COURT: If you want to let them go because of the
7
    expense, I'd certainly understand that --
8
          MR. BREEN: Your Honor, I think it's very unlikely
9
    there are going to be any objections.
10
          THE COURT: The reason I need to do this is, there are
    reasons I have to approve this by year end, or I wouldn't have
11
12
    interrupted you. It has something to do with, what is it, a
13
    corporate transaction?
14
          MR. BREEN: Acquisition.
15
          THE COURT: Yes, an acquisition. So you can find out
    the nitty-gritty details from them, but if there are no
16
17
    objections, this will not take more than three minutes. If
    there are objections, I need to finish it, which is the only
18
19
    reason I'm cutting into your valuable time.
20
          MR. DALY: We'll work with the Court's schedule.
21
          THE COURT: All right, thank you.
22
          MR. DALY: Thank you, Judge.
23
          THE CLERK: Court is in recess.
24
          (Adjourned, 5:03 p.m.)
25
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